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Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

EndoBarrier™ Gastrointestinal Liner for obesity



**Australian
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of New
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PRIORITISING SUMMARY

REGISTER ID S000117

NAME OF TECHNOLOGY ENDOBARRIER™ GASTROINTESTINAL LINER

PURPOSE AND TARGET GROUP TO REDUCE NUTRIENT AND CALORIE UPTAKE IN PEOPLE WITH OBESITY

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|---|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Brazil	✓		
Chile	✓		
USA	✓		
The Netherlands	✓		

IMPACT SUMMARY

The EndoBarrier™ Gastrointestinal Liner (GI Dynamics, Inc., Lexington, MA, United States) is a fluoropolymer liner that is anchored endoscopically in the duodenum to create a duodenal-jejunal bypass, facilitating the reduction of nutrient and caloric uptake by creating a physical barrier between ingested food and the intestinal wall.

BACKGROUND

An obese person is one with a marked degree of overweight whose body mass index (BMI) measures equal to or greater than 30. The BMI is an assessment of a person's weight in relation to their height, and is calculated by dividing a person's weight in

kilograms by the square of their height in metres (i.e. kg/m²) (Australian Institute of Health and Welfare 2010). A standard classification of BMI is as follows:

BMI <18.5: underweight

BMI ≥18.5 and <25: healthy weight

BMI ≥25 and < 30: overweight but not obese

BMI ≥30: obese (World Health Organisation 2000).

The World Health Organisation (WHO) predicts that by 2015 approximately 2.3 billion adults will be overweight, and more than 700 million will be obese (World Health Organisation 2006). The obesity epidemic has led to the introduction of various new treatments in the past decade (Tsemeli and Coumaros 2009). The initial treatments for obesity include dietary management, exercise and behavioural modifications, but in many instances patients do not achieve sustained weight loss. Presently, surgery is considered by many to be the most effective therapy for this complex disorder - particularly for patients with BMI ≥35 with underlying co-morbidities such as diabetes, sleep apnoea and hypertension (Cote et al 2009). Extreme forms of obesity (BMI ≥40) may be unlikely to respond to dietary, behavioural or pharmacological treatment. Relapse rates of up to 90% have been documented for non-surgical treatments of morbid obesity, irrespective of the choice of conservative treatment (Council of Scientific Affairs 1988; Segal et al 1994).

In contrast, clinical trials have demonstrated that surgery can lead to substantial weight loss, and decreases in obesity-related co-morbidities and mortality rates (Stylopoulos et al 2009). However, the patients undergoing these surgical procedures are particularly prone to a range of complications and adverse events. Recently, laparoscopic techniques have become increasingly popular due to their association with low mortality and complication rates. There is also a growing interest in emerging procedures that employ endoluminal technology. Present endoluminal techniques for the treatment of obesity include procedures for preoperative weight loss, revision surgery and stand-alone weight loss procedures. Endoluminal surgery is performed entirely through the gastrointestinal tract utilising flexible endoscopy, and has attracted considerable attention due to its reduced invasiveness and the reversible nature of some of these procedures/technologies. Additionally, further developments in endoluminal bariatric surgery may extend the current indications for intervention to older patients, those with multiple co-morbidities and even patients with mild obesity.

A recent addition to the arsenal of endoluminal procedures for obesity is the EndoBarrier™ Gastrointestinal Liner (GI Dynamics, Inc., Lexington, MA, United States). The EndoBarrier (also known as the duodenal-jejunal bypass sleeve) is a 60-cm long fluoropolymer liner that is anchored endoscopically in the duodenum to create a duodenal-jejunal bypass. The device reduces nutrient and caloric uptake by creating a physical barrier between ingested food and the intestinal wall, thus mimicking the effects of a Roux-en-Y gastric bypass procedure (GI Dynamics 2010).

CLINICAL NEED AND BURDEN OF DISEASE

Australia's obesity rate is among the highest in the world (Australian Institute of Health and Welfare 2010). In 1995, 56% of Australian adults were either overweight or obese (Australian Institute of Health and Welfare 2010). By 2007-2008 the percentage of adults who were overweight or obese had increased by 5 percentage points to 61% (Australian Institute of Health and Welfare 2010).

Being overweight or obese has serious implications towards health. Obesity has been identified as a risk factor for a range of diseases such as osteoarthritis, cardiovascular disease, depression, some cancers, Type 2 diabetes and stroke (Australian Institute of Health and Welfare 2010).

DIFFUSION

The EndoBarrier device does not appear on the Australian Register of Therapeutic Goods and has not received US Food and Drug Administration 510(k) clearance; however, the device does have the European CE mark (GI Dynamics 2009).

There is no indication that the Endobarrier is being utilised in a clinical trial setting within Australia. Therefore, the Endobarrier is yet to emerge within the Australian healthcare system.

COMPARATORS

To date, there is no consensus with regards to the gold-standard bariatric procedure. The selection of the operative technique is often influenced by patient characteristics and surgeon preference. Some of the main bariatric procedures currently utilised are adjustable gastric banding, Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion with duodenal switch (BPD-DS) and sleeve gastrectomy (NIDDK 2009).

The Endobarrier is primarily targeted as a pre-surgical treatment for obesity. This means that it is not intended as a definitive treatment for morbidly obese patients. Therefore, the primary comparators would be dietary or behavioural modifications. In addition, comparators to Endobarrier include other non-surgical/minimally invasive obesity treatments (e.g. StomaPhyX, intragastric balloons) (Cote and Edmundowicz 2009, Overcash 2008).

SAFETY AND EFFECTIVENESS ISSUES

Four randomised controlled trials (RCTs) on the EndoBarrier device were identified and retrieved for inclusion in this summary (Gersin et al 2010; Rodriguez et al 2009; Schouten et al 2010; Tarnoff et al 2009).

Study description

Gersin et al (2010) was a prospective, randomised, unblinded, sham-controlled trial in which 21 patients received the EndoBarrier and 26 patients received sham endoscopy. All patients were aged between 18 and 55 years (mean 44[SD, 9] years) and were refractory to non-surgical weight loss treatment. There were no significant differences between

treatment groups regarding age, BMI or body weight ($P>0.05$). Both arms enrolled more females than men (EndoBarrier 71% female patients and sham endoscopy 89% female patients). EndoBarrier patients appeared to have a greater percentage of co-morbidities than the sham endoscopy group (e.g. hypertension was reported in 57% of the Endobarrier group and 42% of the sham endoscopy group, dyslipidemia was reported in 43% of the Endobarrier group and 23% of the sham endoscopy group, type 2 diabetes mellitus was reported in 67% of the Endobarrier group and 46% of the sham endoscopy group). However, no statistical differences were reported. A total of 10 patients were lost to follow-up at 12 weeks (eight EndoBarrier and two sham endoscopy patients).

Rodriguez et al (2009) was a randomised, single-blind, sham-controlled trial in which 12 patients received EndoBarrier and 6 patients received sham endoscopy. All patients were aged between 18 and 55 years (mean 47 [SD 10] years). There were no significant differences between treatment groups regarding age, gender, body weight, BMI, HbA_{1c}¹, FPC, postprandial glucose area under the curve (AUC), or duration of diabetes ($P>0.05$). Treatment duration was 200 ± 22 days in the EndoBarrier group and 190 ± 44 days in the sham endoscopy group. Patients were followed up at 12 and 24 weeks. At 12 weeks follow-up five EndoBarrier patients (42%) and one sham endoscopy patient (17%) had ceased therapy.

Schouten et al (2010) was a randomised controlled trial in which 30 patients were randomised to receive EndoBarrier plus diet therapy, and 11 patients were randomised to diet therapy alone. Outcome assessors were not reported to have been blinded. Treatment groups were not significantly different for age (EndoBarrier mean 40.9 years [range 20-59] versus diet therapy mean 41.2 years [range 19-57]); weight or BMI ($P>0.05$). EndoBarrier patients suffered more obesity-related complications such as hypertension (15/30, 50% versus diet therapy 5/11, 45%), diabetes (8/30, 27% versus diet therapy 2/11, 18%) and hyperlipidemia (6/30, 20% versus diet therapy 0/11); however, no statistical analysis was reported. The treatment duration for EndoBarrier was mean 35 minutes [range 12-102] for implantation and mean 17 minutes [range 1-6] for explantation. The authors stated that 'intention to treat' was defined as those patients who had been successfully implanted (26 of 30 randomised patients). The study was supported by GI Dynamics.

Tarnoff et al (2009) was stated to be a prospective, randomised controlled trial in which 25 patients received the EndoBarrier and 14 patients received diet therapy. However, the last 15 consecutive patients to enrol in the study were all assigned to the EndoBarrier group in order to increase treatment group numbers. Outcome assessors were not reported to have been blinded. Diet therapy patients were older than EndoBarrier patients (mean 43 ± 10.6 years [range 25-57] versus 38 ± 10.1 years [range 23-56] respectively). Mean BMI was higher in EndoBarrier patients, as was mean body weight. No statistical analysis regarding these between-group differences was provided. Patients were followed up at 12 weeks. Ten diet therapy patients (71.4%) and five EndoBarrier patients (20%) were lost to follow-up.

¹ HbA_{1c} is a test that measures the amount of glycated hemoglobin in your blood.

Safety

Safety outcomes related to the EndoBarrier procedure were reported in all four RCTs (Gersin et al 2010; Rodriguez et al 2009; Schouten et al 2010; Tarnoff et al 2009). One RCT (Schouten et al 2010) noted that there were no procedure-related adverse events during implantation or explantation of the EndoBarrier device. Meanwhile, two RCTs (Gersin et al 2010; Rodriguez et al 2009) reported incidences of procedural nausea (9.3% in Gersin et al 2010 and 4.6% in Rodriguez et al 2009) and procedural vomiting (5.6% in Gersin et al 2010 and 3.1% in Rodriguez et al 2009). In the remaining RCT the sole procedure-related adverse event was non-cardiac chest pain, and explantation was uneventful in all patients (n=25) (Tarnoff et al 2009). Two RCTs reported upon placement difficulties (Gersin et al 2010; Tarnoff et al 2010). In one RCT the EndoBarrier could not be implanted in four patients (19%), due to a short duodenal bulb (n=3) or a combination of patient anatomy and investigator inexperience (n=1) (Gersin et al 2010). In the remaining RCT, five patients (20%) required multiple implantation attempts in the same setting due to difficulties advancing the catheter or positioning the anchor in the duodenal bulb (Tarnoff et al 2009).

Three of the four EndoBarrier RCTs reported no incidences of “severe” adverse events during follow-up (Gersin et al 2010; Rodriguez et al 2009; Schouten et al 2010). Gersin et al (2010) reported that there were no symptoms of biliary obstruction, pancreatic duct obstruction, or obstruction or migration of the device in any patient. “Mild/moderate” adverse events that occurred with the highest frequency in the EndoBarrier group were upper abdominal pain (13%), nausea (5.6%) and vomiting (3.7%). No adverse events were reported for the diet therapy group (Gersin et al 2010). Rodriguez et al (2009) reported that all EndoBarrier patients (100%) experienced at least one episode of mild or moderate abdominal pain and 4 patients had mild or moderate vomiting episodes (abdominal pain: 30.8%, 20 incidences; vomiting: 10.8%, 7 incidences), no such events were reported for the sham group (Rodriguez et al 2009). Schouten et al (2010) stated that all 26 patients (100%) in the EndoBarrier group experienced at least one adverse event during follow-up compared to 3 patients (23.3%) in the diet control group (no P-value stated). Of all the adverse events observed (in both groups), 61.3% were “mild” and 38.7% were “moderate”. Adverse events with the highest frequency in the EndoBarrier group were nausea (76.9%) and upper abdominal pain (50%), both mainly occurring in the first week after the procedure. The investigators also reported that pseudopolyp formation and implant site inflammation (observed during explantation or follow-up endoscopy) were noted in 50.0% and 38.5% of EndoBarrier patients, respectively (Schouten et al 2010).

Tarnoff et al (2009) stated that there were no signs or symptoms of biliary or pancreatic duct obstruction. Five adverse events were considered “serious”: gastrointestinal hemorrhage (n=3), abdominal pain (n=1) and vomiting (n=1). A total of 16 EndoBarrier patients (61.5%) reported at least one adverse event. Of the 56 adverse events observed, a total of 48 (86%) were possibly or definitely related to the EndoBarrier (abdominal pain n=16, nausea n=7, vomiting n=8, abdominal distention n=11, gastrointestinal haemorrhage n=4, constipation n=1, epigastric discomfort n=1) (Tarnoff et al 2009).

Rodriguez et al (2009) reported that a total of 5 EndoBarriers were explanted (41.6%) prematurely: 3 due to adverse events and 2 due to device migration (asymptomatic).

Tarnoff reported that 5 EndoBarriers were removed (19.2%) before the end of the trial due to intraluminal hemorrhage (n=3), sleeve obstruction (n=1) and anchor migration (n=1). Meanwhile Schouten et al (2010) stated that 4 patients (15.4%) had their EndoBarrier removed prior to the 12 or 24 week study period as a result of severe nausea and vomiting (due to sleeve obstruction, n=1), epigastric pain (n=2) and device migration (n=1). Gersin et al (2010) reported that a total of seven EndoBarriers were removed prematurely due to haematemesis (n=3) or abdominal pain, nausea and/or vomiting (n=4).

Effectiveness

All four RCTs on EndoBarrier reported efficacy outcomes (Gersin et al 2010; Schouten et al 2010; Tarnoff et al 2009; Rodriguez et al 2009). In addition to weight loss outcomes, three RCTs reported changes in the severity of co-morbidities (e.g. diabetes/glycemic control) after EndoBarrier implantation (Rodriguez et al 2009; Schouten et al 2010; Tarnoff et al 2009).

In one RCT, weight loss was not significantly different between the EndoBarrier and diet control patients at the first week (Schouten et al 2010). However, at 12 weeks post-implantation, the EndoBarrier group achieved a significant percentage of greater excess weight loss (EWL) compared to the diet control group (19% vs. 6.9%; $P < 0.002$). However, the mean reduction in BMI at 12 weeks was 5.5 kg/m^2 for the EndoBarrier group, which was not significantly different to the 1.9 kg/m^2 change observed in the diet control group. In the 3 patients who retained the device for 24 weeks, the percentage of EWL was 24.3%. However, the diet control group only remained in follow-up for 12 weeks and therefore no statistical comparison could be made. Overall, 88% of EndoBarrier patients achieved $>10\%$ EWL, compared with 27.3% of control patients ($P = 0.05$) (Schouten et al 2010).

Similarly, Tarnoff et al (2009) reported that the average percentage of EWL at 12 weeks post-implantation was significantly greater for the EndoBarrier group ($22.1\% \pm 8\%$) compared to the diet control group ($5.3\% \pm 6.6\%$) ($P = 0.02$). This corresponds to a mean absolute weight loss of $10.3 \pm 3.2 \text{ kg}$ (range: 4.5kg to 18kg) for EndoBarrier patients and $2.6 \pm 3.5 \text{ kg}$ (range: 0kg to 7.7kg) for diet control patients. At the end of this trial, 92% (23/25) of EndoBarrier patients and 21% (3/14) of diet control patients achieved at least 10% EWL ($P = 0.0001$) (Tarnoff et al 2009).

Patients who underwent EndoBarrier implantation were compared to those who received sham endoscopy in two RCTs (Gersin et al 2010; Rodriguez et al 2009). In one RCT the mean reduction in body weight was actually comparable between both treatment arms throughout the first 12 weeks of the study in both intention to treat and per protocol populations (Rodriguez et al 2009). The EndoBarrier arm tended towards achieving more weight loss after week 12; however this did not reach statistical significance. At week 20, mean intention to treat weight reduction was $10.2 \pm 1.3 \text{ kg}$ for the EndoBarrier patients compared to $7.1 \pm 4.3 \text{ kg}$ for the sham patients. By week 24, there were only 3 sham patients left in the study; mean weight loss were similar in both arms (Rodriguez et al 2009). In the second RCT (Gersin et al 2010), significantly more EWL was reported in the EndoBarrier group ($11.9\% \pm 1.4\%$, 95% CI 9.0% to 14.9%) than in the sham endoscopy group ($2.7\% \pm 2.0\%$, 95% CI -1.4% to 6.7%) ($P < 0.001$). In the EndoBarrier

group 62% of patients achieved at least 10% EWL (n=8) at 12 weeks compared with 17% in the sham endoscopy group (n=4) (P=0.01). Total body weight change at week 12 was significantly greater in the EndoBarrier group (-8.2 ± 1.3 kg, 95% CI -10.9 kg to -5.5 kg) compared with the sham endoscopy arm (-2.0 ± 1.1 kg, 95% CI -4.4 kg to 0.3 kg) (P=0.002). This equated to a $5.8\% \pm 0.7\%$ decrease in the EndoBarrier group (95% CI -7.4% to -4.2%) and to a $1.5\% \pm 0.9\%$ decrease in the sham endoscopy group (95% CI -3.3% to 0.3%) (P=0.002).

With regards to diabetic outcomes, Schouten et al (2010) reported that fasting glucose levels and HbA1c values decreased marginally in both EndoBarrier and diet control groups at 12 weeks, but these changes were not statistically significant. Nevertheless, the investigators noted that 6/8 (75%) diabetic patients in the EndoBarrier group decreased their insulin dosages and/or oral anti-diabetic medications after 1 week. At 12 weeks, ongoing improvements were still evident in 5 patients (continuous decrease in medication requirements), whereas one patient completely stopped diabetic medication. One patient did not achieve any decrease in medication intake, while another patient was not accounted for in the results. Tarnoff et al (2009) stated that all 4 diabetic patients in the study (3 randomised to EndoBarrier) improved by week 1 and maintained this status throughout the trial. In one EndoBarrier patient, diabetic status continued to improve and was resolved² at 12 weeks' follow-up.

In the RCT by Rodriguez et al (2009), all patients were diabetics and were being treated with at least one oral anti-diabetic drug (OAD). At week 12, for the intention to treat population, the authors noted that 42% of EndoBarrier patients had ceased treatment with any OAD, while 17% of sham patients had ceased OAD use. In the completer population, 40% of EndoBarrier patients and 25% of sham patients that remained on this study had ceased OAD therapy. At week 12, intention to treat HbA1c values decreased by $1.3 \pm 0.9\%$ for the EndoBarrier arm compared to a decrease of $0.8 \pm 0.3\%$ in the sham arm, which was not significantly different. This was maintained at week 24. In contrast, the change in fasting plasma glucose levels were actually greater for EndoBarrier patients (mean decrease, 50 ± 18 mg/dL) compared to sham patients (mean increase, 25 ± 29 mg/dL) (P=0.042) for the intention to treat population. However, this difference was no longer evident at week 12 and week 24. At week 1 follow up for the completer population, 80% of EndoBarrier patients and sham patients had a reduction in postprandial glucose excursions compared to baseline. However, postprandial plasma glucose area under the curve decreased by 22% from baseline values in the EndoBarrier group compared with a 16% increase in the sham group (P=0.016) for the completer population. This was also evident for the intention to treat population: postprandial plasma glucose AUC decreased by 19% in EndoBarrier patients and increased by 11% in sham patients (P=0.014). There was no change in postprandial insulin levels in either treatment group (Rodriguez et al 2009).

² defined as off medications with normal fasting glucose and normal glycosalated hemoglobin.

COST IMPACT

No cost-utility analysis literature was available for the EndoBarrier. However predictive pricing for the device is estimated at approximately half the cost of laparoscopic banding and a quarter of the cost of gastric bypass (Gersin 2009).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieval material.

OTHER ISSUES

The primary author within Gersin et al (2010) disclosed that he was a consultant to, and financial shareholder in, GI Dynamics. Additionally, this study was supported by funding from GI Dynamics.

Rodriguez et al (2010) disclosed that four of the study's authors were paid consultants for GI Dynamics, one of whom was also a shareholder and medical director of this company.

SUMMARY OF FINDINGS

Three current, randomised controlled trials reported upon a combined total of 88 patients who received EndoBarrier. These trials found that obese patients achieved significantly more weight loss when using the EndoBarrier compared with control treatments. Additionally, the EndoBarrier generally concurrently improved diabetic outcomes. Several patients were unable to receive the EndoBarrier due to positioning difficulties or anatomical restrictions, with one trial indicating a failure rate of 19%. Furthermore, 25 patients (28.4%) required removal of the EndoBarrier, which is of concern since this device is intended for short term use. The most commonly reported adverse events were nausea, vomiting and abdominal pain and adverse events (although not all serious) occurred in 100% of patients in two of the included trials.

Although the EndoBarrier displayed significant efficacy, this is tempered by the high incidence of explantation, adverse events and the fact that most of the trials were sponsored by the device manufacturer (GI Dynamics).

HEALTHPACT ASSESSMENT

Based on the evidence available, Endobarrier appears to have the potential to induce significant weight loss and improve diabetic symptoms. However, additional comparative studies with appropriate controls are necessary as the evidence base of this device is limited and lacks long-term follow-up results. Due to the ongoing interest in minimally invasive treatments for obesity and the prevalence of the disease, it is recommended that the Endobarrier device be monitored for 24 months.

HEALTHPACT ACTION

NUMBER OF STUDIES INCLUDED

Total number of studies	4
Level II intervention evidence	4

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SEARCH CRITERIA TO BE USED

Endobarrier

Endoluminal sleeve

Duodenal-jejunal bypass sleeve

HEALTH PACT DECISION

- | | |
|--|--|
| <input type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |
| <input type="checkbox"/> Refer | <input type="checkbox"/> Decision pending |

PRIORITY RATING

- High** **Medium** **Low**