Cost-Effectiveness Analysis of the EndoBarrier Device in Patients with Type 2 Diabetes

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BACKGROUND

The diabesity pandemic continues unabated despite multiple pharmacotherapy options including injectable glucagon-like peptide-1 receptor agonists (GLP-1RA) e.g. liraglutide, associated with weight loss.

EndoBarrier is an innovative impermeable tubing device (Fig. 1) inserted and removed endoscopically trans-orally after up to 1 year. Its presence in the proximal intestine prevents ingested food from contacting the intestinal mucosa, mimicking the bypass aspect of Roux-en-Y gastric bypass surgery. Treatment with EndoBarrier in patients with diabesity can improve glycaemic control whilst reducing weight.

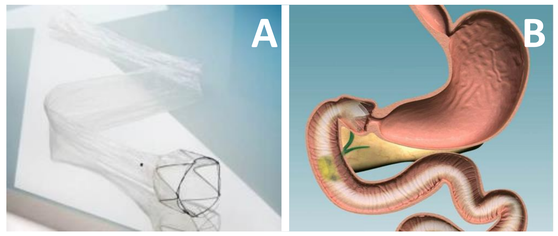


Fig. 1A. *Photograph of Endobarrier with crown anchor in foreground and 60cm in length tubing posteriorly;* ***1B*** *shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.*

AIM

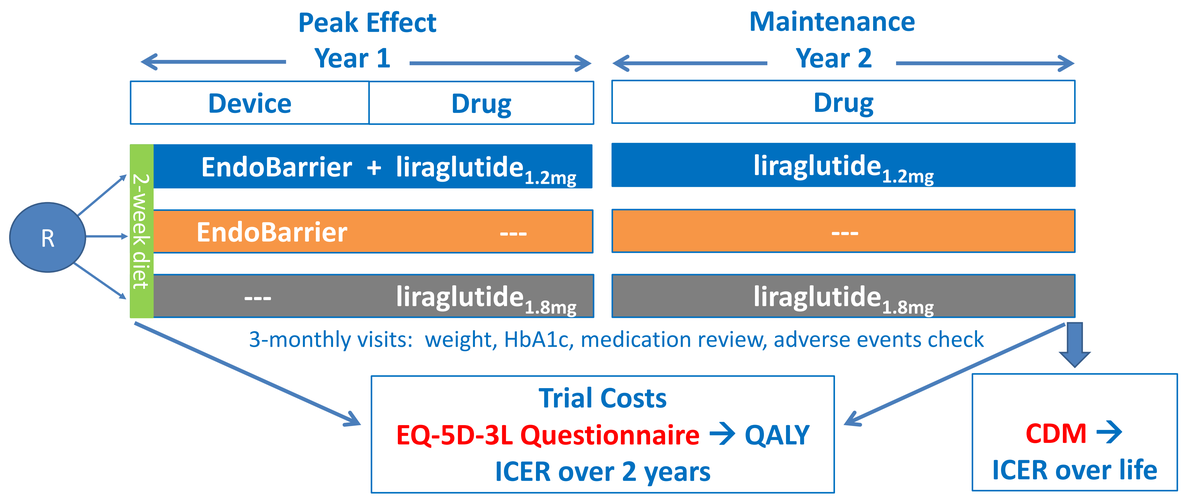
To evaluate the cost effectiveness of the EndoBarrier device with or without liraglutide 1.2mg daily compared to liraglutide 1.8mg daily without EndoBarrier, in patients with type 2 diabetes and obesity from a UK National Health Service perspective.

METHOD

Seventy patients were randomised to one of 3 treatment arms (REVISE-Diabesity ISRCTN00151053, Fig. 2) and followed for two years with the following calculated:

- Quality Adjusted Life-Years (QALYs) using quality of life measured with EQ-5D-3L questionnaires (EuroQoL)
- Treatment costs – planned and related to adverse events
- Incremental cost-effectiveness ratio (ICER) over:
  - a 2-year horizon
  - lifetime, from patient physiological data at 2-years extrapolating outcomes and costs beyond this utilising the Core Diabetes Model (CDM, QuintilesIMS).

Fig. 2. *Study design.*



RESULTS

	EndoLira (n = 24)	Endo (n = 24)	Lira (n = 22)
QALYs over 2 years, mean (sd)	1.60 (0.33)	1.68 (0.20)	1.34 (0.64)
HbA1c at 2 years, mean (sd) [mmol/mol]	64.9 (12.6)	71.5 (11.4)	70.1 (11.7)
BMI at 2 years, mean (sd) [kg/m²]	38.5 (5.2)	39.9 (4.64)	39.6 (4.3)
Adjusted QALY difference*, mean (se)	0.023 (0.09)	0.146 (0.10)	---
Adjusted HbA1c difference*, mean (se)	-5.69 (3.7)	1.07 (3.7)	---
Adjusted BMI difference*, mean (se)	-0.79 (0.78)	-0.54 (0.79)	---
Treatment costs per patient [£]	11,585	10,629	7,501
Adverse event costs per patient [£]	644	2,312	592
Total cost per patient [£]	12,229	12,941	8,092

Table 1. *Costs and QALYs over two years according to treatment arm after imputation of missing data.*

Mean (se) life expectancy (years)	22.48 (0.34)	21.58 (0.32)	21.69 (0.33)
Mean (se) QALYs gained over 50 years	8.91 (0.11)	8.61 (0.10)	8.61 (0.10)
Mean (se) QALYs gained over 2 years	1.21 (0.01)	1.21 (0.01)	1.21 (0.01)
Mean (se) costs accrued over 50 years [£]	139,000 (4,000)	151,000 4,400)	149,000 (4,400)
Mean (se) costs accrued over 2 years [£]	11,000 (400)	11,000 (400)	11,000 (400)
Mean (se) QALYs from 2-50 years	7.70 (0.37)	7.40 (0.37)	7.41 (0.37)
Mean (se) costs from 2-50 years [£]	128,000 (4,000)	139,000 (4,400)	138,000 (4,300)
QALY difference, 2-50 years	0.286	-0.012	-
Cost difference, 2-50 years [£]	-9,823	1,465	-
QALY difference, 0-50 years	0.309	0.134	-
Cost difference, 0-50 years [£]	-5,686	6,314	-

Table 2. *Lifetime Costs and QALYs according to treatment arm.*

Table 1 shows that, at 2 years, QALYs were highest in the Endo group and lowest in the Lira group. After adjustment for baseline differences and relative to the lira group, there was a modest gain in QALYs for EndoLira compared with Lira and a large cost increase; there was a larger gain in QALYs in moving from EndoLira to Endo for a smaller cost increase. As this demonstrated EndoLira was extendedly dominated by Endo, with EndoLira excluded, the ICER for Endo compared with liraglutide was calculated as £33,000 over a 2 year horizon.

Table 2 shows that, over 50 years, life expectancy and QALYs gained were highest in the EndoLira arm and lowest in the Endo arm driven by the relative impact of the interventions on HbA1c at two years. The costs, also driven primarily by HbA1c trajectories, were highest for Endo and lowest for EndoLira. After summing incremental costs and QALYs from the trial with those determined for the period from 2 to 50 years from the CDM, EndoLira dominated both Endo and Lira, generating the most QALYs at the lowest cost. EndoLira was the most likely strategy to be cost-effective across the range of willingness-to-pay values from zero to £50,000. There was a greater than 90% probability that EndoLira was the most cost-effective strategy at commonly accepted threshold willingness-to-pay values for £20,000-£30,000 per QALY gained for the treatment of diabesity.

CONCLUSION

The EndoBarrier device used without liraglutide was cost effective over two years. Over a patient's lifetime, the EndoBarrier device with liraglutide 1.2mg was the most cost effective, driven by its superior glucose-lowering effect.

Our analysis suggests a role for the EndoBarrier device used with GLP-1RA for the control of HbA1c and weight in patients with T2DM and obesity in a UK setting. Further research into strategies to improve maintenance and to confirm the sustainability of gains in HbA1c and weight following removal of the EndoBarrier device are recommended.

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