

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

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BACKGROUND

The EndoBarrier Device

The EndoBarrier device is a bypass liner that is implanted endoscopically via the mouth. It extends 60 cm from the duodenal bulb into the small intestine, excluding ingested food mixing with digestive juices where sited. Treatment with it can reduce the patient's weight and blood glucose.



Fig. 1. Photograph of the EndoBarrier device.

AIM

To evaluate whether or not the EndoBarrier device with or without liraglutide 1.2mg daily is cost effective compared with liraglutide 1.8mg daily patients with obesity and type 2 diabetes from a NHS healthcare perspective.

METHOD

70 patients were randomised into one of the three treatment arms and were followed for two years. Quality of life was measured with EQ-5D-3L and Quality-Adjusted Life Years (QALYs) calculated. Due to the non-negligible amount of missing quality of life and clinical indicator data, multiple imputation of missing outcomes was undertaken. The equipment and personnel involved with the interventions were supplied by the clinical trial from which costs were estimated, this included the costs of adverse events related to treatment. The incremental cost effectiveness ratio (ICER) was calculated over a two-year horizon. The Core Diabetes Model (QuintilesIMS) was used to extrapolate outcomes and costs beyond two years and calculate the lifetime ICER.

RESULTS

The in-trial results can be seen in Table 1. It showed the treatment that resulted in the greatest number of QALYs was the EndoBarrier device alone, this was for both the unadjusted results and after adjusting for baseline characteristics. The results did show that both the EndoBarrier device with 1.2 mg liraglutide and the EndoBarrier device alone resulted in higher quality of life compared with liraglutide alone. However, the EndoBarrier device alone also appeared to raise the HbA1c level whereas the EndoBarrier device with 1.2 mg liraglutide lowered it, which may be significant over the patient's lifetime. Both the EndoBarrier device with 1.2 mg liraglutide and the EndoBarrier device appeared to help the patients lose weight. However, inference from the results is limited due to the small trial. All the confidence intervals around the adjusted QALYs, HbA1c level and weight contained zero which showed the high level of uncertainty around the results.

Table 1 Table of Cost and Benefits per Patient

	EB + L1.2mg	EB	L1.8mg
Unadjusted QALY (SE)	1.59 (0.17)	1.69 (0.17)	1.33 (0.10)
Unadjusted HbA1c (SE) mmol/mol	64.1 (8.1)	74.2 (8.1)	68.9 (5.0)
Unadjusted weight (SE) kg	109.2 (3.8)	109.0 (3.8)	111.5 (2.9)
Adj QALY Diff from lira SE,(CI)	0.03 0.1 (-0.16,0.22)	0.17 0.1 (-0.2,0.36)	-
Adjusted HbA1c Diff from lira SE,(CI)	-6.0 4.9 (-16.0,3.9)	0.56 5.0 (-9.7,10.8)	-
Adjusted weight diff from lira SE,(CI)	-2.1 2.6 (-7.3,3.0)	-1.9 2.6 (-7.1,3.3)	-
Cost of treatment per patient (£)	11,658	10,703	8,154
Cost of treatment all patients (£)	816,088	749,204	570,769
Cost of adverse events (£)	15,834	56,049	13,470
Cost of AE per patient (£)	660	2,335	612
Total Costs per patient (£)	12,318	13,038	8,766

Table 2 Life Time Cost and Benefits per Patient

	EB + L1.2mg	EB	L1.8mg
Quality-adjusted life expectancy (years) per patient	9.20	9.04	8.89
SE	0.37	0.37	0.37
Combined costs per patient (£)	140,216	152,224	146,487
SE	3991	4362	4336

The Core Diabetes Model (CDM) was run for a 50 year time horizon and a two year time horizon. The CDM produced Quality Adjusted Life Expectancy (QALE) for each of the groups, and showed that the EndoBarrier device with 1.2 mg liraglutide had the greatest number of QALYs followed by 1.8 mg liraglutide, with the EndoBarrier device alone having the fewest number of QALYs. The in-trial data was added in to replace the first two years of the CDM as shown in Table 2. The EndoBarrier device with 1.2 mg liraglutide then had a greater number of QALYs than the EndoBarrier device alone and 1.8 mg liraglutide. The lifetime results showed that the EndoBarrier device with 1.2 mg liraglutide dominated the EndoBarrier device alone and 1.8 mg liraglutide. This result stemmed from the EndoBarrier device with 1.2 mg liraglutide lowering the HbA1c level and weight more than the other treatments. This was the key result upon which the lifetime cost effectiveness pivots.

CONCLUSION

The EndoBarrier device alone was cost effective over two years. However, due to the EndoBarrier device with 1.2mg liraglutide lowering the patient's HbA1c level more than the EndoBarrier device alone, it indicated that over a patient's lifetime the EndoBarrier device with 1.2. mg liraglutide was cost effective. Therefore our analysis suggests a role for the EndoBarrier device along with GLP-1RA for the control of HbA1c and weight in patients with T2DM and obesity. Further research to confirm the sustainability of gains in HbA1c and weight following removal of the EndoBarrier device is recommended.