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

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**Abstract:**

**Objective:** There are multiple pharmacotherapy options for type 2 Diabetes Mellitus (T2DM) including injectable glucagon-like peptide-1 receptor agonists (GLP-1RA) e.g. liraglutide. EndoBarrier is an innovative impermeable liner implanted endoscopically into the proximal intestine for up to one year, before removal. We compared the cost effectiveness of three strategies in patients with suboptimally controlled diabetes despite at least 6 months' liraglutide: EndoBarrier combined with 1.2mg liraglutide (E+L); EndoBarrier without liraglutide (E), and 1.8mg liraglutide without EndoBarrier (L) for the treatment of obese patients with T2DM from a National Healthcare perspective.

**Methods:** Seventy patients were randomised to one of three treatment arms (REVISE-Diabetes ISRCTN00151053) and followed for two years. Quality of life was measured with EQ-5D-5L and Quality Adjusted Life-Years (QALYs) calculated. Treatment costs were estimated including 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 estimate outcomes and costs beyond two years based on patient physiological data at two years, allowing calculation of the lifetime ICER.

**Results:** At two years, QALYs were highest in the E group, followed by E+L, after adjustment for baseline differences. Costs were lowest in the L group and highest in the E group. The ICER of E compared with L was £25,130. However, E+L generated the largest reductions in both HbA<sub>1c</sub> level (-0.6% compared with L) and weight (-2.1 Kg compared with L) at two years. Consequently, over the lifetime of a patient E+L generated the most QALYs and the lowest cost.

**Conclusion:** Our analysis suggests a role for EndoBarrier along with GLP-1RA therapy for the control of HbA<sub>1c</sub> and weight in patients with T2DM. Further research to confirm the sustainability of gains in HbA<sub>1c</sub> and weight following removal of EndoBarrier is recommended.

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