A duodenal sleeve bypass device added to intensive medical therapy for obesity with type 2 diabetes: a RCT

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Plain English summary

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Plain English summary

Obesity is a worldwide issue and is associated with complications such as type 2 diabetes mellitus. Both conditions cause suffering to the individual and are costly for health-care services. The duodenal–jejunal sleeve bypass (EndoBarrier®; GI Dynamics Inc., Boston, MA, USA) is a removable tubular device that is implanted using a telescope into the small intestine via the mouth and stomach without the need for surgery.

In this study, 170 patients were recruited across two hospital sites. All participants received lifestyle modification advice and optimisation of their diabetes control with intensive medical therapy. Half of the patients also received the endoluminal duodenal–jejunal bypass liner for 12 months and then all patients were seen periodically over a further 12-month period to have their progress monitored. The main aim of this study was to identify the proportion of patients who achieved glucose improvement as defined by the International Diabetes Federation. The study also investigated the degree of weight loss achieved and the safety of the device. To understand how the endoluminal duodenal–jejunal bypass liner works, additional studies were conducted to measure the brain response to food using brain imaging techniques, body sensitivity to insulin and food choices, and to analyse the breakdown products produced by bacteria in our bodies.

Both treatments produced similar improvements in glucose control, but people in the endoluminal duodenal–jejunal bypass liner group lost more weight and achieved better blood pressure control than those in the control group while the device was in place, but not after its removal. Significant reactions and side effects occurred more frequently in the endoluminal duodenal–jejunal bypass liner group than in the group that did not receive the device, and the majority of these side effects were deemed to be definitely related to the duodenal–jejunal bypass liner. At 6 months, the degree to which the body's cells respond to the hormone insulin and take up glucose from the blood was improved in the duodenal–jejunal bypass liner group. There were no differences in brain responses to food or eating behaviour between the groups. Breakdown products of metabolism detected in blood, urine and faeces were found to vary significantly between the treatment groups.

Overall, these results indicate that the endoluminal duodenal–jejunal bypass liner is not better than intensive medical therapy for glucose control. We showed some benefit to weight loss at 1 year but not at 2 years. The evidence suggests that the device does not appear to be a cost-effective strategy for glucose control or weight loss.

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This report

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