

EndoBarrier treatment for longstanding type 2 diabetes and obesity: A comparison of the outcomes with an implantation period of 9 months versus 12 months in 90 consecutive EndoBarrier treated patients

REJ Ryder¹, M Yadagiri¹, W Burbridge¹, SP Irwin¹, T Bashir², MC Wyres¹, ML Cull¹, JP Bleasdale³, RA Allden⁴, EN Fogden⁴, M Anderson⁴ and P Sen Gupta^{1,5}
 Departments of ¹Diabetes, ²Dietetics, ³Anaesthetics, ⁴Gastroenterology, City Hospital, Birmingham, UK, ⁵Guy's and St Thomas' Hospitals, London, UK

BACKGROUND

EndoBarrier (GI Dynamics, Boston, USA), is a 60 cm endoscopically implanted, impermeable intestinal liner which reduces weight and improves glycaemic control during a year of treatment in patients with type 2 diabetes and obesity¹. Many of the serious adverse events (SAE's) associated with EndoBarrier occur during the last three months of treatment and reducing the period of implantation to 9-months may reduce the complication rate².



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

AIMS and METHODS

We aimed to: i) assess the safety and efficacy of EndoBarrier in 90 consecutive patients with longstanding poorly controlled type 2 diabetes and obesity by monitoring outcomes in a registry³; ii) assess safety and efficacy for 9-months vs 12-months implantation in these patients.

RESULTS

Table 1: 78/90 (87%) patients attended review at both 9-months and 12-months after EndoBarrier implantation. Baseline characteristics:

| Parameter | N=78 |
|---|-----------------|
| Age (years) | 51.3±8.4 |
| Sex (% male) | 49 |
| Ethnicity (% white ethnicity) | 59 |
| BMI (kg/m ²) | 41.5±7.1 |
| HbA1c (mmol/mol) | 79.3±20.1 |
| (%) | 9.4±1.8 |
| Diabetes duration (median (IQR) (years) | 11.0 (7.0-17.2) |
| Taking insulin (%) | 53 |

Table 2: During EndoBarrier treatment, there was no difference between the fall in HbA1c at 9-months vs 12-months (p=0.95). The weight loss at 9-months was 1.6 kg less than that at 12-months (p<0.001).

| Parameter | n | Baseline | 9-months | 12-months | Difference 9-months vs baseline | Difference 12-months vs baseline | P-value baseline vs 9-months | P-value baseline vs 12-months | P-value difference 9- vs 12-months |
|------------------|----|------------|------------|------------|---------------------------------|----------------------------------|------------------------------|-------------------------------|------------------------------------|
| Weight (kg) | 78 | 120.0±26.8 | 106.3±27.7 | 104.6±27.9 | -13.8±7.7 | -15.4±8.4 | <0.001 | <0.001 | <0.001 |
| HbA1c (mmol/mol) | 78 | 79.3±20.1 | 58.9±14.7 | 58.8±13.2 | -20.5±18.8 | -20.5±19.4 | <0.001 | <0.001 | 0.95 |
| HbA1c (%) | 78 | 9.4±1.8 | 7.5±1.3 | 7.5±1.2 | -1.9±1.7 | -1.9±1.8 | <0.001 | <0.001 | 0.95 |

Serious adverse events

Table 3: By one year, 14/90 (15.6%) patients required early EndoBarrier removal for serious adverse events (SAEs): five gastrointestinal haemorrhage, two liver abscess, one other intra-abdominal abscess, one cholecystitis and five for gastrointestinal symptoms. All made a full recovery and most experienced benefit despite the complication. 6/14 (43%) of these SAEs would have been avoided by EndoBarrier removal at 9-months (including one liver abscess and one cholecystitis):

| Serious Adverse Event | All | Before 9-months | After 9-months |
|--|-----------|-----------------|----------------|
| Early removal because of gastrointestinal haemorrhage | 5 | 5 | 0 |
| Early removal because of liver abscess | 2 | 1 | 1 |
| Early removal because of gastrointestinal symptoms - EndoBarrier had migrated | 2 | 1 | 1 |
| Early removal because of gastrointestinal symptoms | 2 | 0 | 2 |
| Early removal because of cholecystitis | 1 | 0 | 1 |
| Abdominal abscess due to small perforation of bowel in relation to EndoBarrier | 1 | 1 | 0 |
| Early removal because of liner obstruction and gastrointestinal symptoms | 1 | 0 | 1 |
| Total | 14 | 8 | 6 |

CONCLUSION

Our data demonstrates EndoBarrier as highly effective in people with longstanding poorly controlled type 2 diabetes and obesity. Reducing the implantation period from 12-months to 9-months would have resulted in slightly less weight loss (1.6 kg) but no difference in the considerable improvement in HbA1c and would have led to a 43% reduction in SAEs requiring early removal. These data support a change in the recommended implantation period for EndoBarrier from 12-months to 9-months. As endoscopy units are ubiquitous, delivery of EndoBarrier treatment could be relatively straightforward.

References:

1. Ryder, REJ et al. Br J Diabetes 2019;19:110-117.
2. Ryder, REJ et al. Diabetes Care 2023;46:e89-e91
3. Ryder, REJ et al. Practical Diabetes 2022; 39(3): 13-16