



First Risk-Benefit Data from the Worldwide EndoBarrier Registry

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ABSTRACT

Uncertainty exists about risk:benefit of proximal intestinal exclusion with Endobarrier (EB), a novel endoscopic duodenal jejunal liner device for obesity, both with and without diabetes. In view of this, during 2017, an independent, secure, on-line registry was established under the auspices of the Association of British Clinical Diabetologists, for the collection of safety and efficacy data worldwide. As of December 2017, data had been entered on 403 patients {age 51.3 ± 11.8 year, 62% male, 89% euroid, 74% diabetes, BMI 42.6 ± 10.2 kg/m²} from 13 centres in 4 countries: Australia, Austria, Czech Republic and United Kingdom. EB led to many benefits, including: in those with both baseline and explant data, mean ± SD weight fell by 14.5 ± 10.3 kg from 125.3 ± 26.7 to 110.8 ± 26.4 kg (n = 265 p<0.001), HbA1c by 1.4 ± 1.6%, from 8.7 ± 1.8 to 7.2 ± 1.2% (n = 195, p<0.001) and systolic BP fell from 138.5 ± 18.1 to 130.0 ± 17.2 mmHg (n = 149, <0.001). There were 23 (5.7%) serious adverse events (SAE) and 37 (9.2%) less serious AEs (Table 4). All SAE patients made a full recovery. The median (range) weight loss in those with early removal for GI bleed was 6.5 (0-29) and with early removal for liver abscess was 17.2 (7-21) kg. Some SAEs could have been avoided if patients had adhered to guidelines. The benefits of EB therapy are likely to reduce the complications of diabetes. This 1st international data from the EB registry suggests that the likely benefits of EB, far outweigh the risks.

BACKGROUND

EndoBarrier® (GI Dynamics, Boston, USA), also known as the duodenal-jejunal bypass liner, is a 60 cm long impermeable fluoropolymer sleeve which is implanted by endoscopy into the first part of the small intestine where it remains for about 1 year (Figure 1). It is held in place by a nitinol anchor, such that food passes through it without coming into contact with the small intestine, thereby interfering with the normal digestive processes that occur in this region¹. The endoscopic insertion and removal of EndoBarrier are day case procedures, performed in less than an hour under general anaesthesia or heavy sedation. This form of reversible bariatric procedure has been shown to reduce weight and improve glycaemic control in patients with diabetes and obesity^{1,2}.

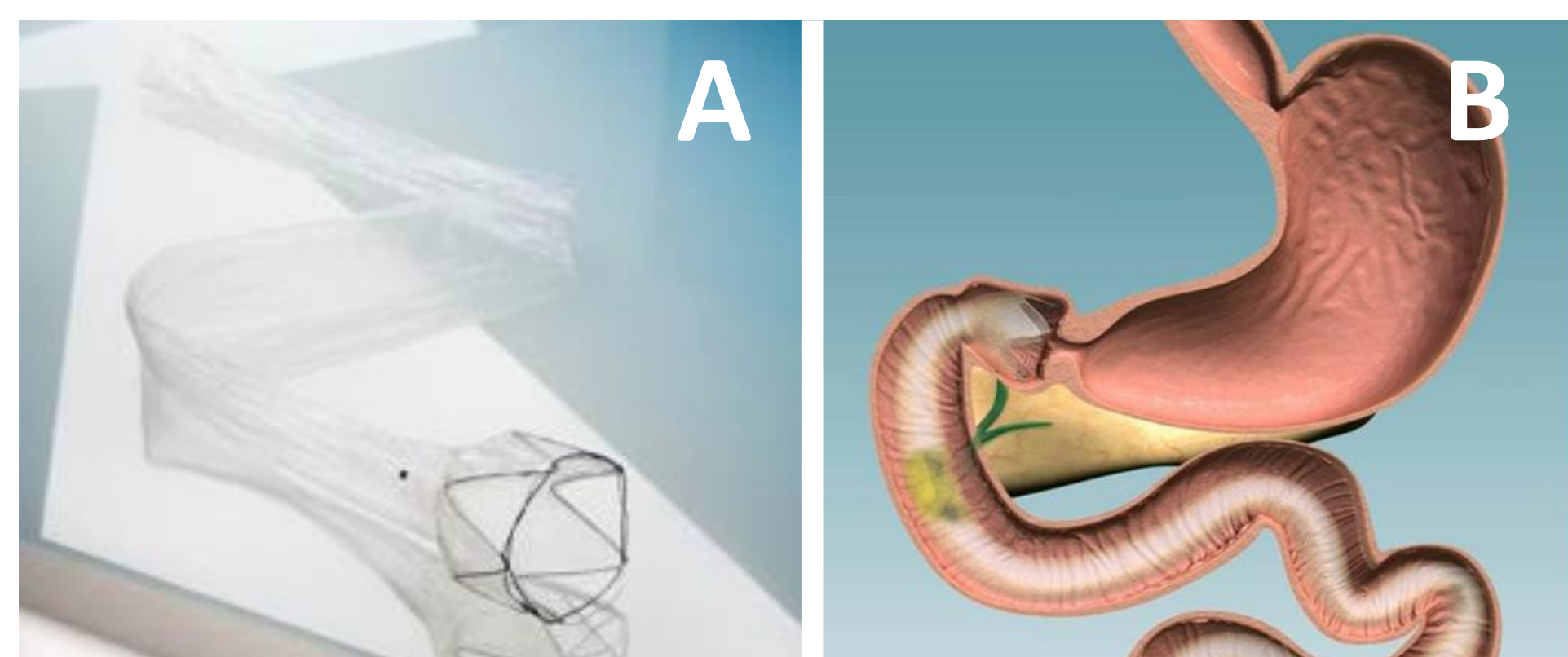


Fig. 1A. Photograph of Endobarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIM

Nevertheless uncertainty exists about risks versus benefits of EndoBarrier. In view of this, during 2017, an independent, secure, on-line registry was established under the auspices of the Association of British Clinical Diabetologists (ABCD), for the collection of safety and efficacy data of EndoBarrier treated patients worldwide.

METHOD

We invited EndoBarrier users from centres worldwide to register to enter the before and after data from their EndoBarrier treated patients into the registry.

RESULTS

As of December 2017, data had been entered on 403 EndoBarrier treated patients from 13 centres in 4 countries: Australia, Austria, Czech Republic and United Kingdom. The demographics of these patients are shown in Table 1.

Table 1: Baseline demographics of the 403 patients

Parameter	n=403
Age (years)	51.3±11.8
Sex (% male)	61.8
Ethnicity (% Euroid)	89.3
BMI (kg/m ²)	42.6±10.2
Diabetes (%)	74

EndoBarrier led to many benefits, including: in those with both baseline and explant data, mean ± SD weight fell by 14.5 ± 10.3 kg from 125.3 ± 26.7 to 110.8 ± 26.4 kg (n = 265 p<0.001), HbA1c by 1.4 ± 1.6%, from 8.7 ± 1.8 to 7.2 ± 1.2% (n = 195, p<0.001) and systolic BP fell from 138.5 ± 18.1 to 130.0 ± 17.2 mmHg (n = 149, <0.001) (Table 2).

Table 2: Changes in weight, HbA1c and Systolic BP

Parameter	n	Baseline	EndoBarrier Explant	Difference	P-value
Weight (kg)	256	125.3±26.7	110.8±26.4	-14.5±10.3	<0.001
HbA1c (%)	195	8.7±1.8	7.2±1.2	-1.4±1.6	<0.001
Systolic BP (mmHg)	149	138.5±18.1	130.0±17.2	-14.3±17.0	<0.001

Table 3: HbA1c response according to baseline HbA1c

HbA1c Range (%)	n	Baseline	At Removal	Difference	P value
All HbA1c	195	8.7±1.8	7.2±1.2	-1.4±1.6	<0.001
All HbA1c ≥ 7	162	9.1±1.6	7.4±1.0	-1.7±1.6	<0.001
All HbA1c ≥ 7.5	144	9.4±1.6	7.5±1.1	-1.8±1.6	<0.001
All HbA1c ≥ 8	116	9.8±1.5	7.7±1.1	-2.1±1.7	<0.001
All HbA1c ≥ 9	71	10.7±1.3	7.8±1.2	-2.8±1.5	<0.001
HbA1c ≥ 8-10	73	8.8±0.6	7.5±1.0	-1.3±1.1	<0.001
HbA1c ≥ 8-10.5	83	9.0±0.7	7.5±1.0	-1.4±1.2	<0.001
HbA1c ≥ 8-11	89	9.1±0.8	7.6±1.0	-1.5±1.2	<0.001
HbA1c ≥ 8-12	104	9.4±1.2	7.7±1.1	-1.8±1.4	<0.001

Fall in HbA1c

The fall in HbA1c found in the whole group was affected by the fact that a quarter of the patients did not have diabetes, and many of those with diabetes the glycaemic control was good. Analysis of the data according to baseline HbA1c is shown in Table 3 and this data clearly shows that the higher the baseline HbA1c the greater the impact of EndoBarrier treatment.

Serious Adverse Events

There were 23 (5.7%) serious adverse events and 37 (9.2%) less serious adverse events (Table 4). All SAE patients made a full recovery. The median (range) weight loss in those with early removal for gastrointestinal bleed was 6.5 (0-29) kg and with early removal for liver abscess was 17.2 (7-21) kg. Some serious adverse events could have been avoided if patients had adhered to guidelines (for examples see poster 2087).

Table 4. Serious adverse events in 403 Endobarrier treated patients.

Serous Adverse Event	n	%
Early removal because of GI bleed	15	3.7
Early removal because of liver abscess	4	1.0
Early removal because of pancreatitis	2	0.5
Early removal because of cholecystitis	1	0.2
Liver abscess post-prolonged implant*	1	0.2
Total	23	5.7
Less serious adverse event	n	%
Precautionary hospitalisation because of transient GI symptoms - removal not required	12	3.0
Early removal because of GI symptoms - Endobarrier had migrated	8	2.0
Early removal because of GI symptoms	8	2.0
Early removal because of liner obstruction	3	0.7
Minor GI bleeding. Endobarrier not removed	3	0.7
Hospitalisation because difficult removal - needed two attempts	2	0.5
Deep venous thrombosis 5 days after implantation led to early removal so that patient could be treated with anticoagulants	1	0.2
Total	37	9.2

✓ GI = gastrointestinal. *This patient had nearly 2 years Endobarrier treatment; he lost 37 kg.

SUMMARY

In this first analysis from the worldwide EndoBarrier registry, the mean weight loss during the period of EndoBarrier implantation was 14.5 kg with associated improvements in glycaemic control and blood pressure. The higher the baseline HbA1c the greater the fall in HbA1c with a mean fall of 2.8% with those with a baseline HbA1c ≥ 9%. The rate of serious adverse events was 5.7% with the majority of these (3.7%) being gastrointestinal bleeds. The rate of early removal for hepatic abscess (1%) was noticeably less than that the 3.5% rate found in the US pivotal trial³. All patients with a serious adverse event made a full recovery and most experienced considerable benefit from the treatment despite the adverse event.

CONCLUSION

The effects of EndoBarrier therapy on glycaemic control, weight and blood pressure are likely to reduce the complications of diabetes. This 1st international data from the EndoBarrier worldwide registry suggests that the likely benefits of EndoBarrier treatment, far outweigh the risks.

REFERENCES

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