



Duodenal jejunal bypass liner (DJBL) for treatment of type 2 diabetes and obesity: glycaemic and CVD risk factor improvements vs risks among 1068 patients treated worldwide

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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}.

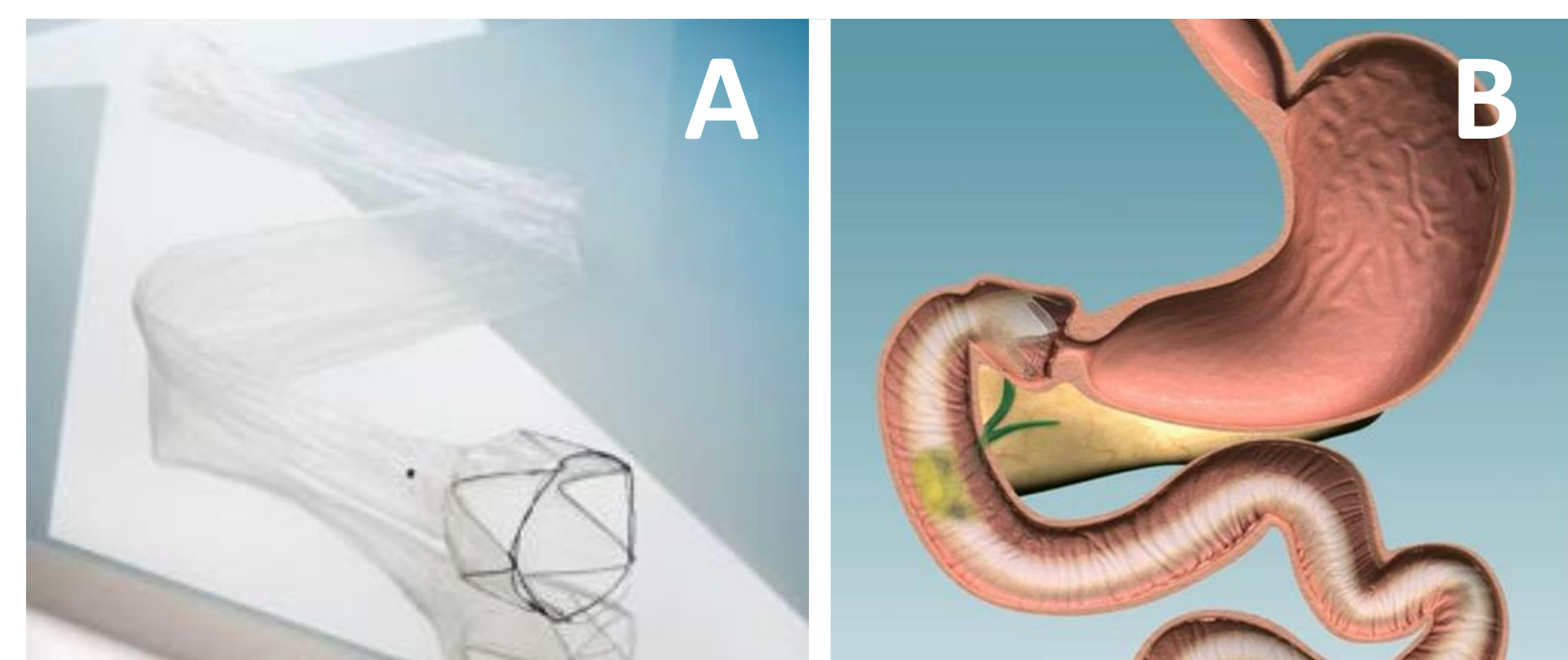


Fig. 1A. Photograph of EndoBarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

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.

REFERENCES

- Ryder REJ et al. Br J Diabetes 2018;18:14-17
- Jirapinyo P et al. Diabetes Care 2018;41(5):1106-1115
- See <http://gidynamics.com/2016/06/23/final-efficacy-and-safety-results-of-u-s-endo-trial-announced-at-ada/>

RESULTS

As of April 2023, data had been entered on 1068 EndoBarrier treated patients from 35 centres in 10 countries: Australia, Austria, Brazil, Czech Republic, England, Germany, Israel, Netherlands, Scotland, and Slovenia. The demographics of these patients are shown in Table 1.

Table 1: Baseline demographics of the 1068 patients

Parameter	n=1068
Age (years)	52.2±11.4
Sex (% male)	51.7
BMI (kg/m ²)	41.1±8.8
Diabetes (%)	83.5

EndoBarrier led to many benefits, including: in those with both baseline and explant data, mean ± SD weight fell by 13.5 ± 9.7 kg from 120.3 ± 25.3 to 106.8 ± 23.8 kg (n = 856 p<0.001), HbA1c by 1.3 ± 1.5%, from 8.4 ± 1.8 to 7.1 ± 1.3% (n = 678, p<0.001), systolic BP fell from 135.7 ± 18.0 to 129.5 ± 17.0 mmHg (n = 448, <0.001) and cholesterol fell from 4.8 ± 1.3 to 4.2 ± 1.0 mmol/L (n = 467, <0.001) (Table 2).

Table 2: Changes in weight, HbA1c, systolic BP and cholesterol

Parameter	n	Baseline	EndoBarrier Explant	Difference	P-value
Weight (kg)	856	120.3±25.3	106.8±23.8	-13.5±9.7	<0.001
HbA1c (mmol/mol)	678	67.9±19.7	54.0±14.0	-13.8±15.9	<0.001
Systolic BP (mmHg)	448	135.7±18.0	129.5±17.0	-6.3±19.2	<0.001
Cholesterol (mmol/L)	467	4.8±1.2	4.2±1.0	0.6±1.0	<0.001

Table 3: HbA1c response according to baseline HbA1c

HbA1c Range (mmol/mol)	n	Baseline	At removal	Difference	P-value
All HbA1c	678	67.9±19.7	54.0±14.0	-13.8±15.9	<0.001
All HbA1c ≥ 53	534	74.7±16.2	57.7±13.0	-17.1±16.2	<0.001
All HbA1c ≥ 64	388	80.8±15.0	60.1±13.6	-20.7±16.9	<0.001
All HbA1c ≥ 75	222	90.0±13.7	63.0±14.6	-27.0±17.8	<0.001
All HbA1c ≥ 86	119	98.9±13.0	64.3±16.0	-34.6±17.9	<0.001
All HbA1c ≥ 97	56	108.5±13.4	67.2±17.8	-41.3±19.7	<0.001

Fall in HbA1c

The fall in HbA1c found in the whole group was affected by the fact that over 16.5% 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 45 (4.2%) serious adverse events and 143 (13.4%) less serious adverse events (Table 4). All SAE patients made a full recovery and most derived significant benefit despite the setback. Some serious adverse events could have been avoided if patients had adhered to guidelines.

Table 4. Serious adverse events in 1068 EndoBarrier treated patients (GI = gastrointestinal).

Serious Adverse Event	n	%
Early removal because of GI bleed (removal: by endoscopy = 24/25; by laparoscopy = 1/25)	25	2.3
Liver abscess (early removal = 9/12; found at time of routine explant = 3/12)	12	1.1
Liver abscess after prolonged implant (1/2 = nearly 2 years; 1/2 = 16 months)	2	0.2
Early removal because of pancreatitis	2	0.2
Early removal because of cholecystitis	2	0.2
Early removal because of liner obstruction - surgical removal required*	1	0.1
Abdominal abscess due to small perforation of bowel in relation to EndoBarrier	1	0.1
Total	45	4.2
Less Serious Adverse Event	n	%
Precautionary hospitalisation because of transient GI symptoms - removal not required	44	4.1
Early removal because of GI symptoms	40	3.7
Early removal because of GI symptoms - EndoBarrier had migrated	28	2.6
Early removal because of liner obstruction	10	0.9
Hospitalisation because difficult removal - needed two attempts	6	0.6
Minor GI bleeding. EndoBarrier not removed	5	0.5
Precautionary hospitalisation because of transient GI problems at time of removal	4	0.4
Transient obstruction of device cleared at endoscopy - device not removed	3	0.3
Transient obstruction of device cleared by gastrografin - device not removed	1	0.1
Liver abscess after 5 weeks treated successfully with antibiotics without early removal	1	0.1
Precautionary early removal because of asymptomatic EndoBarrier migration	1	0.1
Total	143	13.4

*Extraction hood came off during removal and EndoBarrier became stuck in the oesophagus requiring removal through a small incision in the side of the neck

SUMMARY AND CONCLUSION

In this analysis from the worldwide EndoBarrier registry, the mean weight loss during the period of EndoBarrier implantation was 13.5 kg with associated improvements in glycaemic control, blood pressure and cholesterol. The higher the baseline HbA1c the greater the fall in HbA1c with a mean fall of 3.7% with those with a baseline HbA1c ≥ 11%. The rate of serious adverse events was 4.2% with the majority of these (2.3%) being gastrointestinal bleeds.

The rate of early removal for hepatic abscess (1.1%) 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. The effects of EndoBarrier therapy on glycaemic control, weight and blood pressure are likely to reduce the complications of diabetes. This international data from the EndoBarrier worldwide registry suggests that the likely benefits of EndoBarrier treatment, outweigh the risks.