

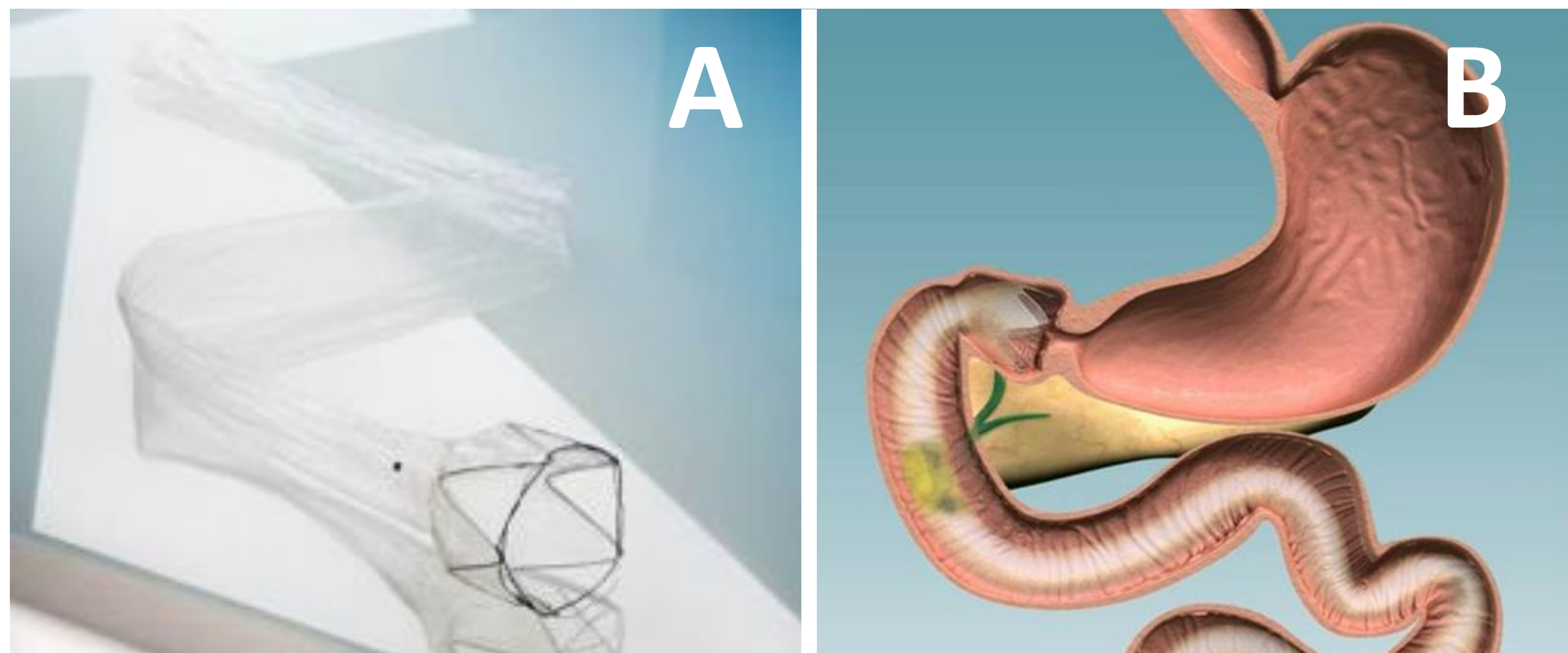
# DUODENAL JEJUNAL BYPASS LINER FOR DIABESITY – RISK VERSUS BENEFIT DATA FROM THE ASSOCIATION OF BRITISH CLINICAL DIABETOLOGISTS (ABCD) WORLDWIDE ENDOBARRIER REGISTRY

B. Ryder<sup>1</sup>, M. Lynne<sup>2</sup>, H. Frydenberg<sup>2</sup>, S. Fishman<sup>3</sup>, R. Cohen<sup>4</sup>, C. de Jonge<sup>5</sup>, J. Greve<sup>5</sup>, J. Bascomb<sup>6</sup>, J. Bessell<sup>6</sup>, J. McMaster<sup>7</sup>, G. Holtman<sup>7</sup>, G. Rich<sup>7</sup>, J. Collins<sup>8</sup>, L. Kow<sup>8</sup>, P. Pferschy<sup>9</sup>, H. Sourij<sup>9</sup>, J. Byrne<sup>10</sup>, J. Mason<sup>11</sup>, J. Teare<sup>12</sup>, M. Benes<sup>13</sup>.

<sup>1</sup>Birmingham, UK. <sup>2</sup>Richmond, Australia. <sup>3</sup>Tel Aviv, Israel. <sup>4</sup>São Paulo, Brazil. <sup>5</sup>Maastricht, Netherlands. <sup>6</sup>AOS, Adelaide, Australia. <sup>7</sup>Brisbane, Australia. <sup>8</sup>ABC, Adelaide, Australia. <sup>9</sup>Graz, Austria. <sup>10</sup>Southampton, UK. <sup>11</sup>Manchester, UK. <sup>12</sup>London, UK. <sup>13</sup>Prague, Czech Republic.

## BACKGROUND

EndoBarrier (GI Dynamics, Boston, USA), is a 60 cm endoscopically implanted, impermeable intestinal liner which reduces weight and improves glycaemic control over up to 1-year of treatment in patients with type 2 diabetes and obesity.



**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.

## AIMS and METHODS

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. 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 October 2018, data had been entered on 540 EndoBarrier treated patients from 13 centres in 7 countries: Australia, Austria, Brazil, Czech Republic, Israel, Netherlands and United Kingdom. The demographics of these patients are shown in Table 1.

**Table 1:** Baseline demographics of the 540 patients

Parameter	n=540
Age (years)	52.1±10.7
Sex (% male)	61
Ethnicity (% European)	85
BMI (kg/m <sup>2</sup> )	41.3±10.0
Diabetes (%)	64.2

**Table 2:** EndoBarrier led to many benefits, including: in those with both baseline and explant data, changes in weight, HbA1c, Systolic BP and cholesterol:

Parameter	n	Baseline	EndoBarrier Explant	Difference	P-value
Weight (kg)	447	120.7±26.4	107.1±24.8	-13.6±10.1	<0.001
HbA1c (%)	334	8.2±1.8	6.9±1.1	-1.2±1.4	<0.001
Systolic BP (mmHg)	189	138.7±18.3	130.3±17.1	-8.5±20.2	<0.001
Cholesterol (mmol/L)	247	4.7±1.2	4.2±1.0	-0.5±1.0	<0.001

**Fall in HbA1c:** The fall in HbA1c found in the whole group was affected by the fact that 40% 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.

**Table 3:** HbA1c response according to baseline HbA1c

HbA1c Range (%)	n	Baseline	At Removal	Difference	P value
All HbA1c	334	8.2±1.8	6.9±1.1	-1.4±1.2	<0.001
All HbA1c ≥ 7	246	8.9±1.5	7.3±1.0	-1.6±1.4	<0.001
All HbA1c ≥ 7.5	212	9.2±1.4	7.4±1.0	-1.8±1.4	<0.001
All HbA1c ≥ 8	169	9.6±1.4	7.5±1.0	-2.0±1.5	<0.001
All HbA1c ≥ 9	95	10.5±1.2	7.7±1.1	-2.8±1.4	<0.001

## Serious Adverse Events

There were 30 (5.6%) serious adverse events and 64 (11.9%) 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 7.4 (0-29) kg and with early for liver abscess was 17.2 (7-24.5) kg. Some serious adverse events could have been avoided if patients had adhered to guidelines.

**Table 4:** Serious adverse events in 540 EndoBarrier treated patients

Serous Adverse Event	n	%
Early removal because of GI bleed	18	3.3
Liver abscess (early removal = 6/7; found at time of routine explant = 1/7)	7	1.3
Early removal because of pancreatitis	2	0.4
Early removal because of cholecystitis	1	0.2
Abdominal abscess due to small perforation of bowel in relation to Endobarrier	1	0.2
Liver abscess after prolonged implant*	1	0.2
<b>Total</b>	<b>30</b>	<b>5.6</b>
Less serious adverse event	n	%
Precautionary hospitalisation because of transient GI symptoms - removal not required	17	3.1
Early removal because of GI symptoms	17	3.1
Early removal because of GI symptoms - EndoBarrier had migrated	14	2.6
Minor GI bleeding. EndoBarrier not removed	5	0.9
Early removal because of liner obstruction	5	0.9
Hospitalisation because difficult removal - needed two attempts	3	0.6
Transient obstruction of device cleared at endoscopy - device not removed	2	0.4
Precautionary early removal because of asymptomatic EndoBarrier migration	1	0.2
<b>Total</b>	<b>64</b>	<b>11.9</b>

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

## SUMMARY

In this analysis from the worldwide EndoBarrier registry, the mean weight loss during the period of EndoBarrier implantation was 13.6 kg with associated improvements in glycaemic control, blood pressure and weight. 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 5.6% with the majority of these (3.3%) being gastrointestinal bleeds. The rate of removal for hepatic abscess (1.3%) during up to 1-year of treatment was noticeably less than that the 3.5% rate found in the US pivotal trial<sup>1</sup>. 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, blood pressure and cholesterol are likely to reduce the complications of diabetes. This international data from the EndoBarrier worldwide registry suggests that the likely benefits of EndoBarrier treatment, far outweigh the risks.

**Reference:** See <http://gidynamics.com/2016/06/23/final-efficacy-and-safety-results-of-u-s-endo-trial-announced-at-ada/>