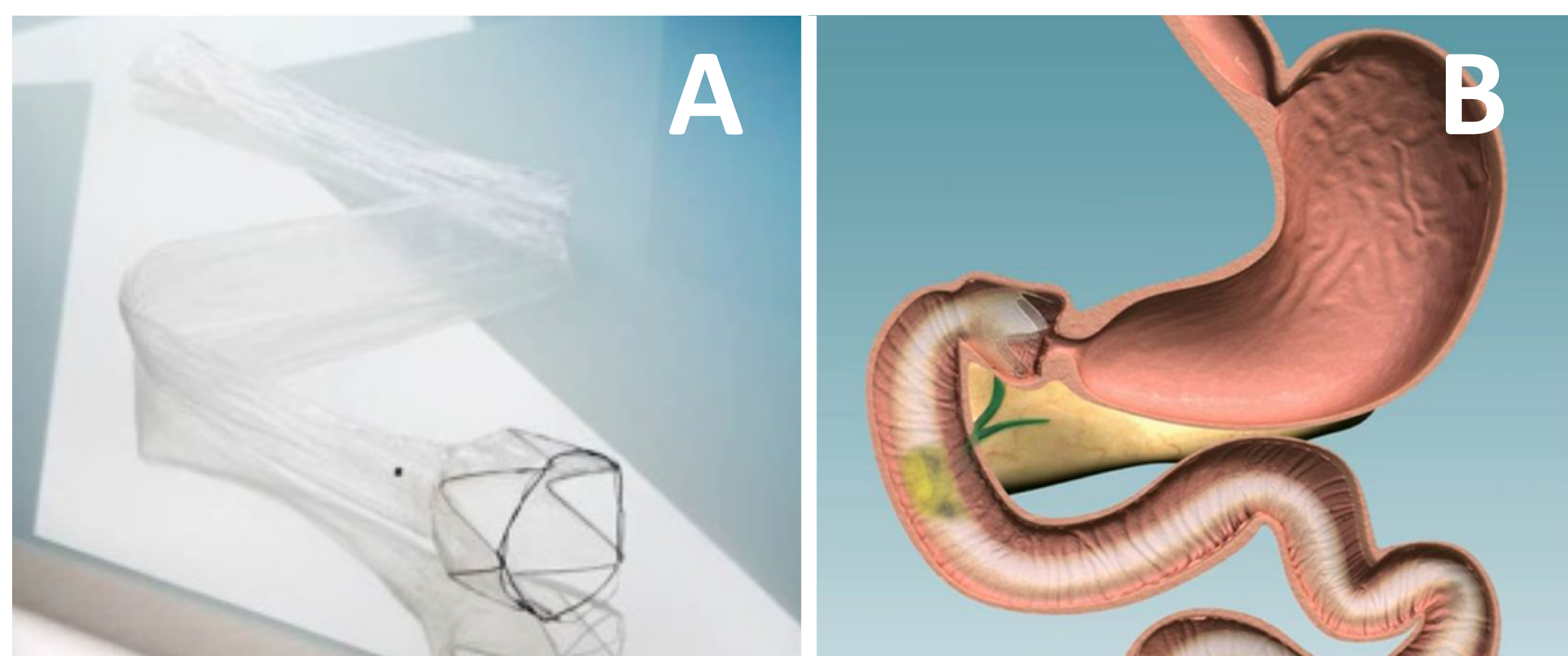


# UK first NHS EndoBarrier service for advanced type 2 diabetes and obesity: one year outcomes in all patients treated

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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). This form of reversible bariatric procedure has been shown to reduce weight and improve glycaemic control in patients with 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.

## AIM

We aimed establish an NHS service to offer EndoBarrier treatment to patients with advanced diabetes and to assess its safety and efficacy by monitoring outcomes in a registry.

## METHOD

Since October 2014 we implanted 62 EndoBarriers in our NHS service and by November 2018 all were explanted.

## RESULTS

**Table 1.** Baseline characteristics of 61 patients with implant and explant data.

Parameter	N=61
Age (years)	51.4±7.2
Sex (% male)	54.1
Ethnicity: % White	57.4
% Afro-Caribbean	16.4
% Asian-Indian	26.2
Smoking: % Never Smoked	54.1
% Past Smoker	26.2
% Current Smoker	19.7
Diabetes duration (Median (IQR) (years))	12.0 (8.0-19.5)
Taking insulin (%)	57.4

8/61(13%) patients required early removal (three for gastrointestinal haemorrhage, two for liver abscess, one because of another abscess, two because of gastrointestinal symptoms); all made a full recovery and derived considerable benefit despite the setback. In some patients these problems were related to non compliance with advice given.

**Table 2.** The impact of EndoBarrier treatment on mean±SD weight, HbA1c and CVD risk factors and alanine-aminotransferase (ALT – a liver fat marker) in 61 patients. There were highly significant falls in all parameters involved in CVD risk assessment other than HDL cholesterol which remained unchanged.

Parameter	Baseline	At explant	Difference	P-value
Weight (kg)	122.6±27.9	106.7±28.9	-15.9±8.5	<0.001
BMI (kg/m <sup>2</sup> )	41.9±7.4	36.2±7.6	-5.7±3.2	<0.001
HbA1c (mmol/mol)	80.2±22.5	56.5±11.5	-23.7±21.4	<0.001
HbA1c (%)	9.5±2.1	7.3±1.1	-2.2±2.0	<0.001
Systolic blood pressure (mmHg)	138.5±15.0	125.8±14.6	-12.7±16.2	<0.001
Cholesterol (mmol/L)	4.7±1.4	3.9±0.9	-0.86±1.13	<0.001
HDL (mmol/L)	1.13±0.27	1.10±0.30	0.04±0.22	0.135
ALT (U/l)	33.2±19.8	19.5±11.4	-13.7±20.1	<0.001
Insulin daily dose (Median (IQR) (n=35)*)	100(60-135)	40(0-70)	-60	<0.001

\*10 of the 35 (28.6%) patients discontinued insulin

**Table 3.** EndoBarrier impact on 10-year CV risk as assessed by the UKPDS risk engine (<https://www.dtu.ox.ac.uk/riskengine>)

### Endobarrier impact on 10-year cardiovascular risk with UKPDS engine (n=61)

	Before Endobarrier	At Endobarrier removal	P value	Absolute risk reduction	Cases saved (out of 100)	Numbers needed to treat
CHD	15.8±11.8	9.0±6.0	<0.001	-6.8 ±7.6	6.8	14.7
Fatal CHD	11.4±10.1	5.6±4.7	<0.001	-5.7±6.7	5.7	17.5
Stroke	5.90±4.71	4.84±3.70	<0.001	-1.06±1.50	1.06	94.3
Fatal stroke	0.94±0.89	0.61±0.52	<0.001	-0.33±0.54	0.33	303.0

#### Interpretation:

- According to UKPDS risk engine **about 8 patients out of 100** will not have a coronary heart disease or stroke event over the next 10 years because of Endobarrier treatment about **6 lives will be saved**

## CONCLUSION

In the first NHS service with EndoBarrier it was used in patients with longstanding poorly controlled diabetes and obesity that was refractory to standard treatments. EndoBarrier resulted in considerable weight loss, improvement in glycaemic control, reduction in a marker of fatty liver, improvement in cardiovascular risk and reduction in the need for insulin. Patients reported considerable increase in fitness and well-being. All patients with early removal because of serious adverse events made a full recovery and derived considerable benefit despite the setback. Such serious adverse events can be reduced by full compliance with advice given. EndoBarrier treatment requires only a relatively simple endoscopy procedure and it deserves further investigation as a potential treatment for wider use in refractory diabetes, given the high cardiovascular and microvascular risk of these patients.