UK FIRST NATIONAL HEALTH SERVICE (NHS) ENDOBARRIER SERVICE FOR UNCONTROLLED DIABESITY SHOWS THE METABOLIC IMPROVEMENTS 6-MONTHS AFTER ENDOBARRIER REMOVAL ARE WELL MAINTAINED

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BACKGROUND

EndoBarrier (GI Dynamics, Boston, USA), is a 60 cm endoscopically implanted intestinal liner which reduces weight and improve glycaemic control in patients with diabetes and obesity.

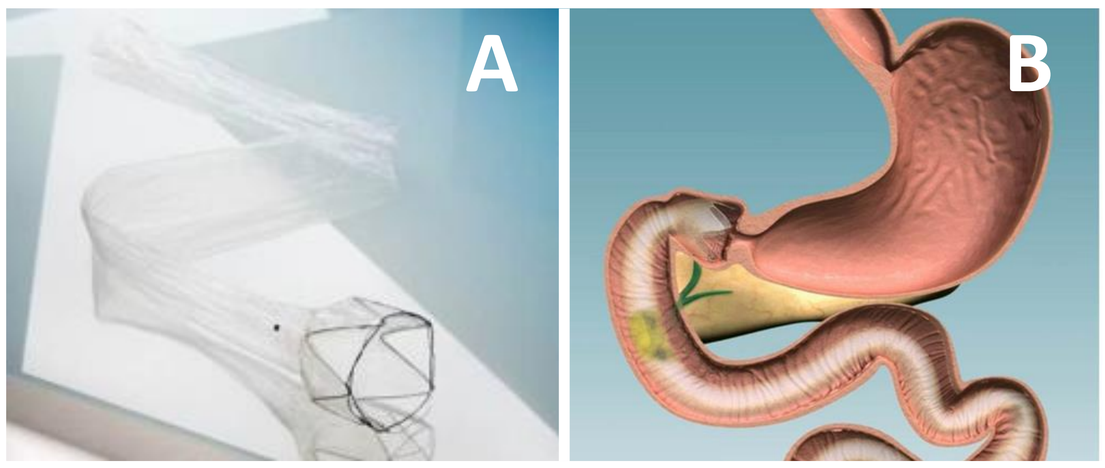

Fig. 1A. Photograph of EndoBarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIMS and METHODS

We aimed to: i) establish an NHS service to offer EndoBarrier treatment to patients with advanced diabesity; ii)to assess its safety and efficacy by monitoring outcomes in a registry; iii) to assess maintenance off efficacy 6-months after removal.

RESULTS

Table 1: So far 53 patients completed 6 months post EB; 43/53 (81%) attended follow up. Baseline characteristics, n=43:

Parameter	N=43
Age (years)	51.6±6.4
Sex (% male)	58.1
Ethnicity (% Europid)	53.5
BMI (kg/m^2)	42.0±8.3
HbA1c (mmol/mol) (%)	83.2±22.2 9.8±2.0
*Diabetes duration (years)	12.0(6-20)
Taking insulin (%)	60.5

Table 2: Outcomes at explant of EndoBarrier; n=43

Parameter	Baseline	EB Explant	Difference	P-value
Weight (kg)	123.9±30.1	108.1±31.4	-15.7±8.9	<0.001
BMI (kg/m^2)	42.0±8.3	36.4±8.7	-5.6±3.4	<0.001
HbA1c (mmol/mol)	83.2±22.2	57.5±12.9	-25.7±21.4	<0.001
HbA1c (%)	9.8±2.0	7.4±1.2	-2.4±2.0	<0.001
Systolic blood pressure (mmHg)	139.6±15.6	125.4±14.8	-14.3±16.7	<0.001
ALT (U/l)	30.6±19.4	19.0±10.2	-11.5±18.5	<0.001
Insulin daily dose* (n=26)	109(58-146)	30(0-72)	-79	<0.001

*Median(IQR). 8 of the 26 (30.8%) patients discontinued insulin

Early removal of EndoBarrier: 6/53 (11.3%) patients had early Endobarrier-removal: 4 GI bleed, 1 liver abscess and 1 GI symptoms. All 6 had full recovery after removal and most experienced benefit despite the setback. All other patients achieved a full year of EndoBarrier treatment.

6 months after the removal of EndoBarrier, 29/43(67%) had maintained the improvement (Figure 3a).

Figure 2: 29/43 (67%) of the patients had maintained the treatment effect at 6 months post explant

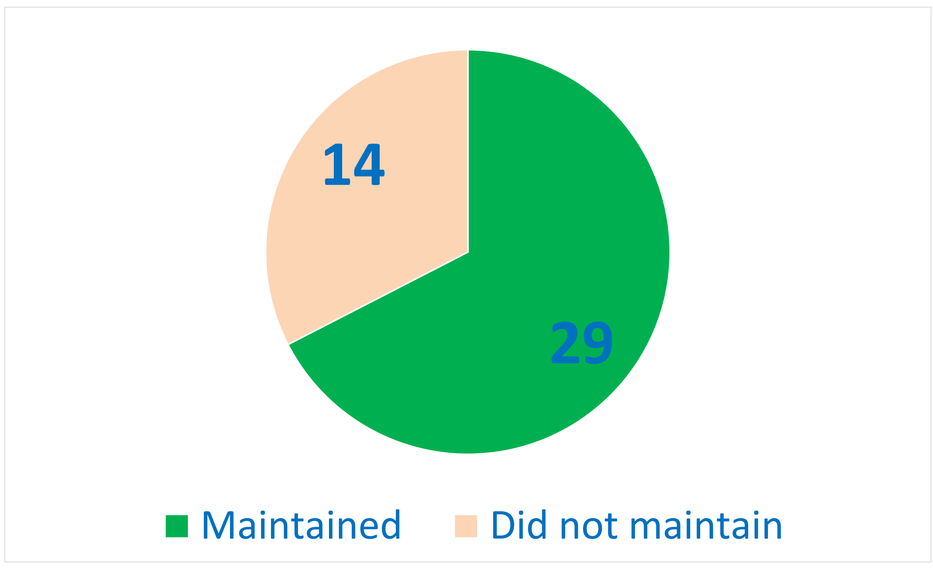

Figure 3: The weight and HbA1c at baseline, at explant and 6 months after explant in the 29/43 (67%) who maintained the improvement (Figure 3a) and 14/43 (23%) who deteriorated (Figure 3b).

Figure 3a:

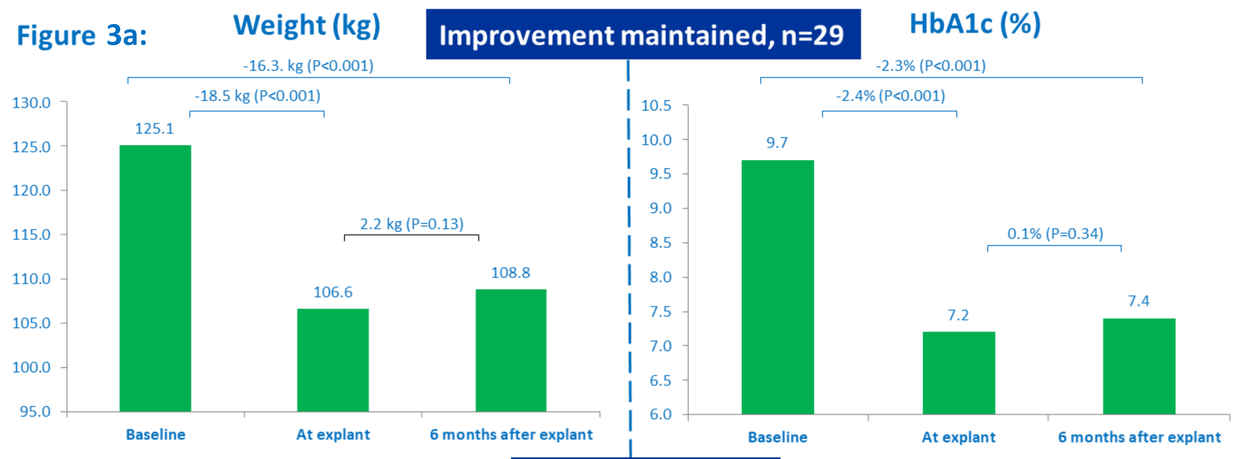

Figure 3b:

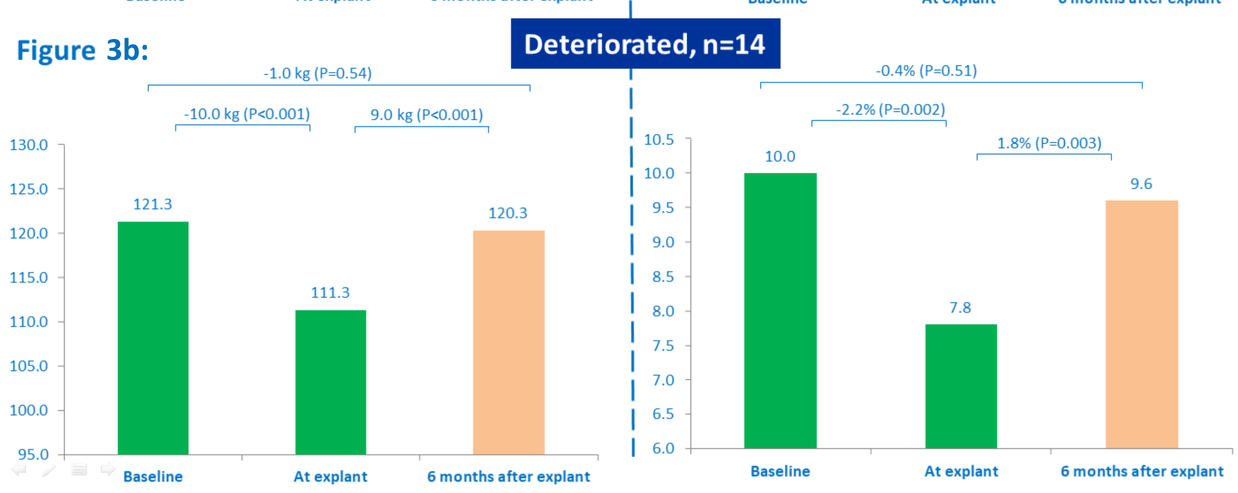

Table 3: The patients who went on to deteriorate (Figure 3b had had less fall in weight and HbA1c during the period of EndoBarrier treatment than those who maintained (Figure 3a):

	Weight loss during EndoBarrier treatment	Fall in HbA1c during EndoBarrier treatment
Maintained (n=29)	18.5 kg	2.4%
Deteriorated (n=14)	10.0 kg	2.2%

Of the 14 whose weight and/or HbA1c deteriorated (Figure 4b), 9/14(64%) had depression or bereavement.

CONCLUSION

Our data demonstrate Endobarrier as highly effective in patients with refractory diabesity with maintenance of improvement after EndoBarrier removal in 67%. These data are supportive of risk:benefit being strongly towards benefit and they support the continuance of EndoBarrier as an important treatment option for refractory diabesity. As endoscopy units are ubiquitous, our service could be readily disseminated.

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