

Institution of the UK's first National Health Service Endobarrier service for type 2 diabetes and obesity

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BACKGROUND

Our institution leads a UK, multicentre, randomised controlled trial (REVISE-Diabetesy ISRCTN00151053) investigating the interaction of Endobarrier therapy, a 60cm endoscopically implanted proximal intestinal liner, with glucagon-like peptide-1 drug therapy. The Endobarrier is implanted by endoscopy for up to 1 year before endoscopic removal.

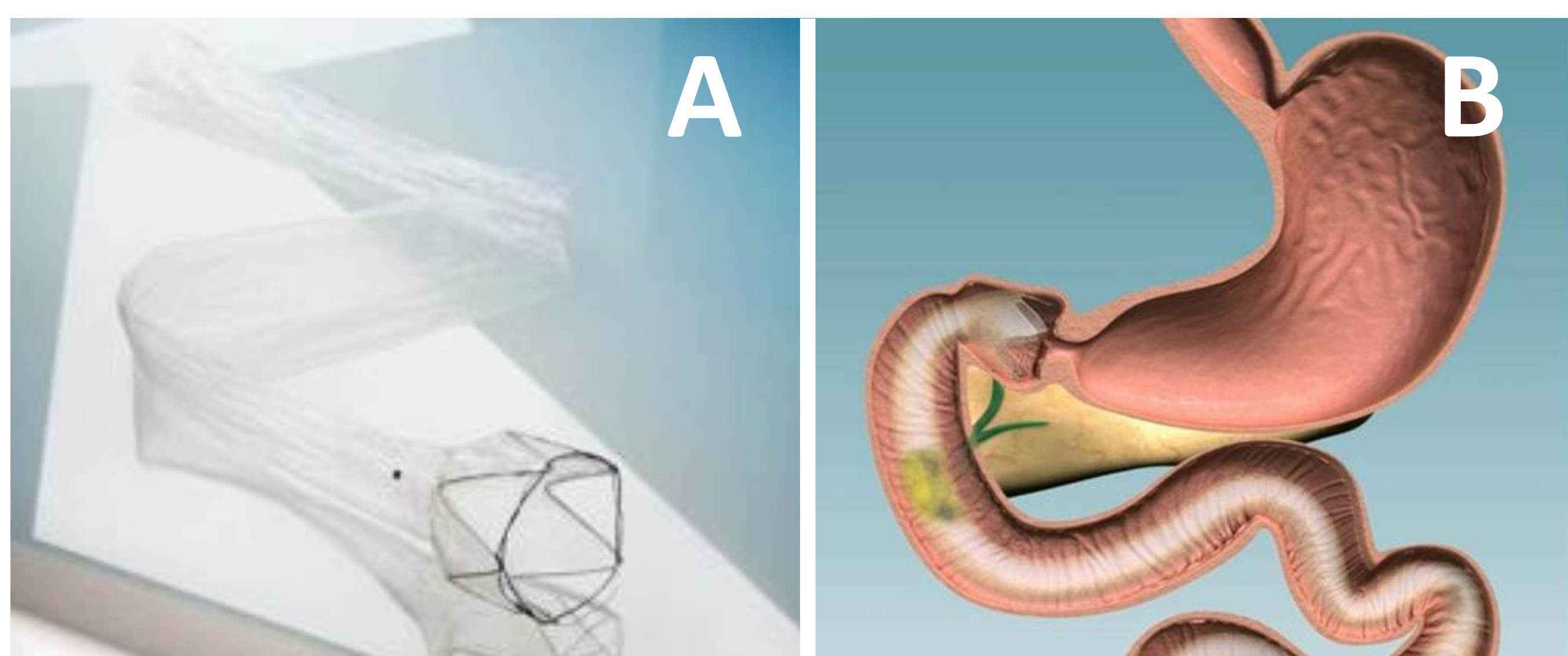


Fig. 1A. Photograph of Endobarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIM

To evaluate whether acquired experience could translate into establishment of an effective and safe NHS Endobarrier service in patients with diabetes.

METHOD

We initiated:

- i) an NHS Endobarrier service for patients with suboptimally controlled type 2 diabetes and obesity, involving:
 - design of a comprehensive 2-year patient pathway
 - consultation with relevant teams and patients
 - management support
 - payment by results funding system (code FZ71C - £790 Endobarrier procedures and device cost £3300 incl VAT)
- ii) a secure online registry supported by ABCD to monitor outcomes.

RESULTS

Since Oct 2014, 59/146 (40.4%) referrals to the service have been accepted for Endobarrier treatment. To date 48 devices have been implanted.

Table 1. Baseline characteristics

Parameter	N=25
Age (years)	51.9±7.5
Sex (% male)	56.0
Ethnicity (% Caucasian)	44.0
BMI (kg/m ²)	41.1±8.9
HbA1c (mmol/mol)	81.2±24.7
(%)	9.6±2.2
*Diabetes duration (years)	12.0(8.5-21.0)
Taking insulin (%)	60.0

Table 2. 1-year outcomes

Parameter	Baseline	1 year	Difference	P-value
Weight (kg)	118.5±27.7	102.2±28.2	-16.3±10.0	<0.001
BMI (kg/m ²)	41.1±8.9	35.0±8.7	-6.1±3.7	<0.001
HbA1c (mmol/mol)	81.2±24.7	56.4±24.7	-24.8±25.0	<0.001
HbA1c (%)	9.6±2.2	7.4±1.1	-2.1±2.1	<0.001
Systolic blood pressure (mmHg)	137.7±13.5	126.0±16.5	-11.6±19.0	0.005
ALT (U/l)	32.0±20.5	17.4±9.8	-14.6±17.2	<0.001
insulin daily dose (n=15)	104(60-135)	12(0-65)	-92	0.003

*6 of the 15 (40%) patients discontinued insulin

Fig. 3. Patient satisfaction – NHS Friends and Family Test

“How likely would you be to recommend this treatment to friends and family?”

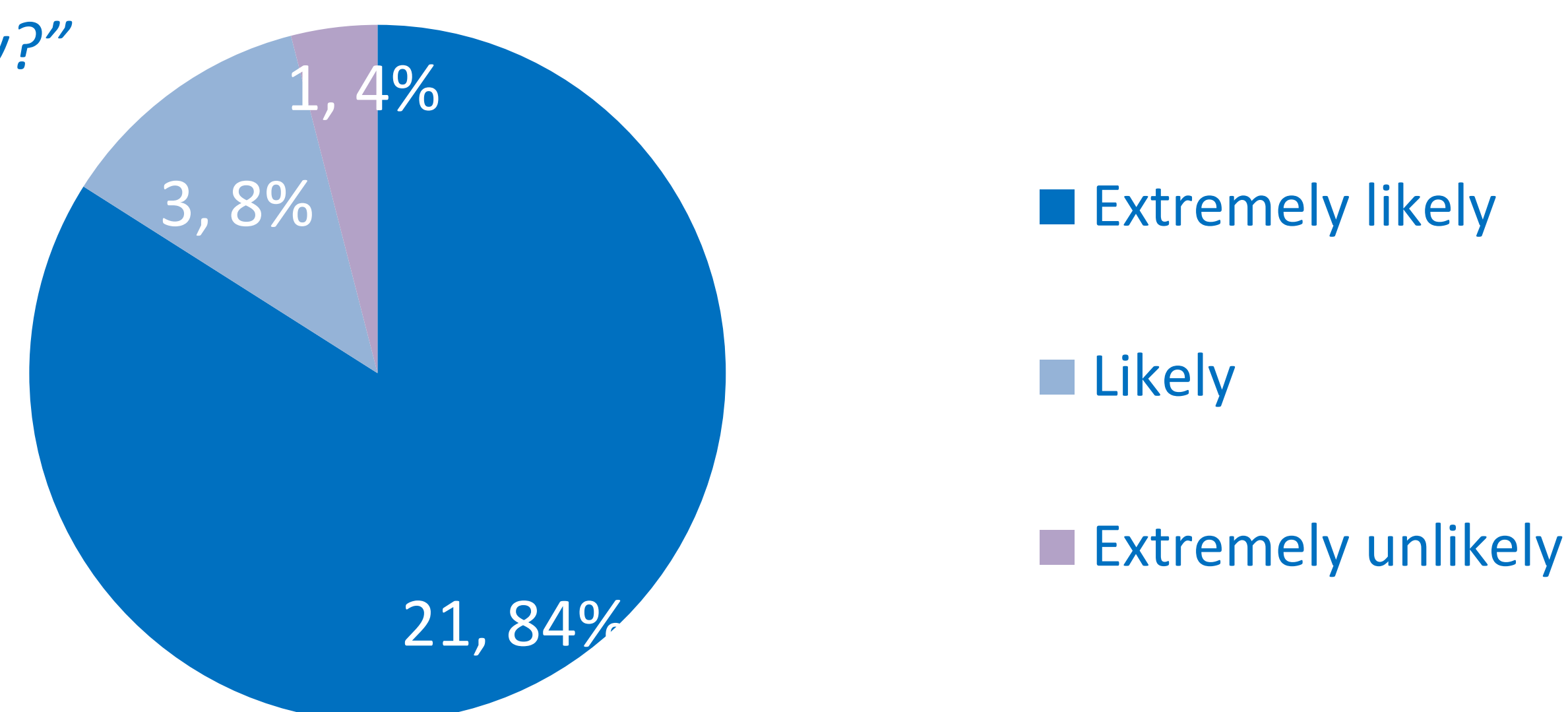
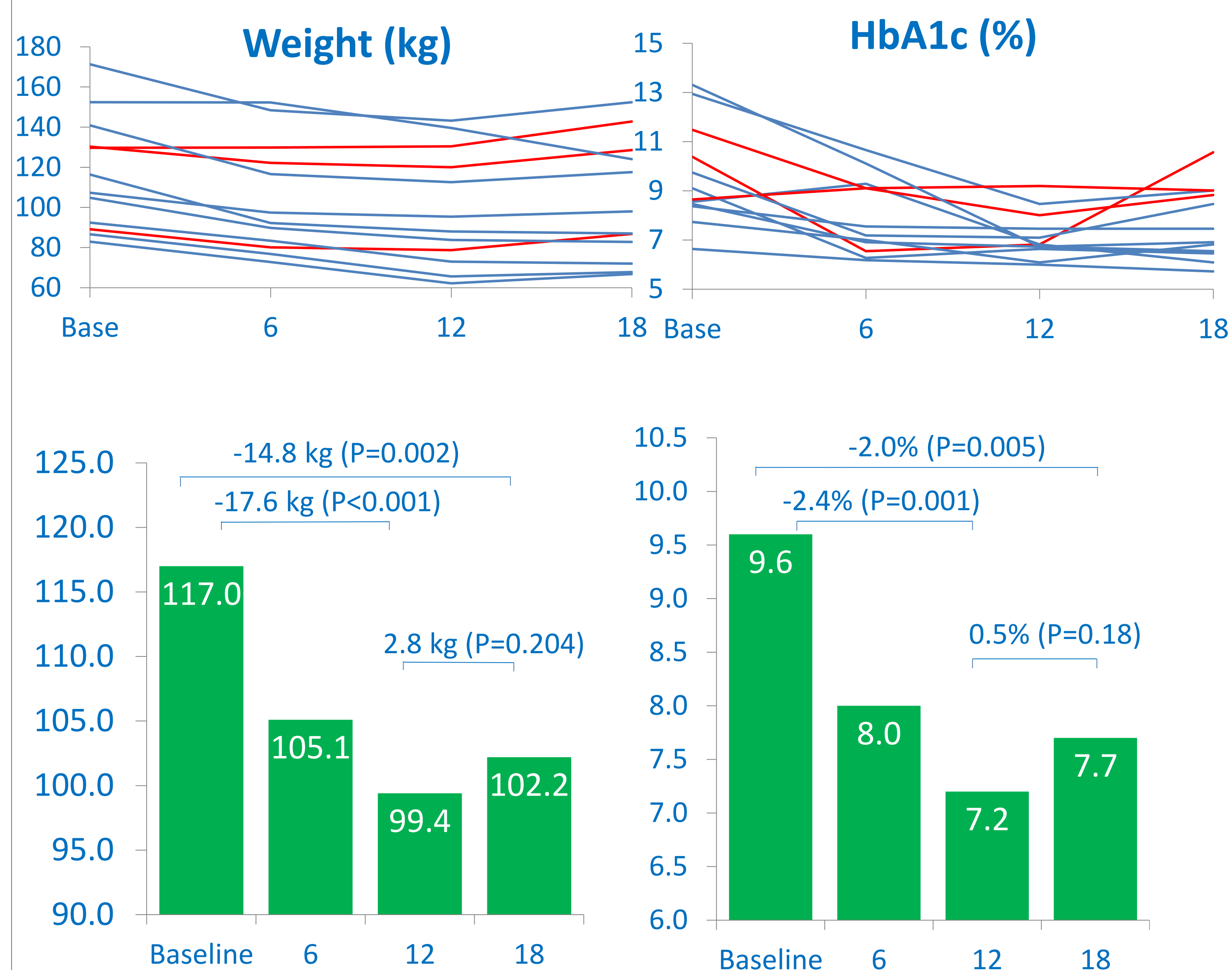


Fig. 4. First 12 NHS Endobarrier patients 6-months explant: Weight and HbA1c change over time (individual plots)



CONCLUSION

We have translated our research programme into an inaugural NHS service, which demonstrates Endobarrier to be highly effective in patients with refractory diabetes. There are high patient satisfaction levels and an acceptable safety profile. As endoscopy units are ubiquitous, our service could be readily disseminated, with the registry useful for on-going monitoring nationwide. Important lessons learnt include cautious selection of patients and patient education is paramount for treatment success.