Sandwell and West Birmingham Hospitals
NHS Trust

UK first NHS Endobarrier service for diabesity: outcomes in the first 30 patients to reach six months after explanation of the device

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Background

Our institution led a UK, multicentre, randomised controlled trial (REVISE-Diabesity 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.

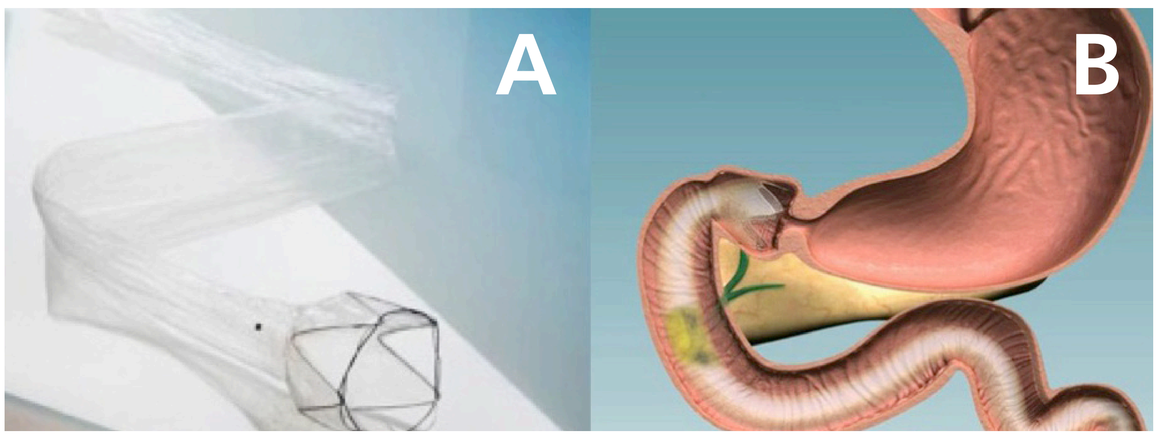

Fig. 1A. Photograph of Endobarrier with crown anchor in foreground and tubing posteriorly; 1B shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

Aims

To evaluate whether acquired experience could translate into establishment of an NHS Endobarrier Service in patients with diabesity that:

1. Is effective during the device implant
2. Maintains effect 6-months after removal
3. Is safe and well tolerated

Method

i) We initiated 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
   - funding system agreed with local service commissioners

ii) We primed patients to maintain improvements after, by suggesting institution of behaviour changes during Endobarrier.

iii) We established a secure online registry supported by ABCD to monitor outcomes.

Results

Since Oct 2014 until Oct 2017, 59 devices have been implanted in our service. We report here the first 30 patients to complete six months post-Endobarrier. Baseline characteristics are shown in table 1.

The metabolic changes whilst the device was in place and after its removal in these 30 patients are shown in table 2. Following removal of Endobarrier 3/30(10%) patients did not attend for follow up. Of 27/30(90%) who have reached six months post-Endobarrier, 19/27(70%) maintained the improvements shown in table 2 (mean±SD weight = 101.3±28.9 kg; HbA1c = 56.6±9.6 mmol/mol). Median(IQR) insulin dose fell further to 18(0-54) units. Of the 8 whose weight and/or HbA1c deteriorated, 6/8(75%) had depression.

Table 1. Baseline characteristics

Parameter	N=30
Age (years)	51.8±7.0
Sex (% male)	57.6
Ethnicity (% Europid)	46.7
BMI (kg/m2)	41.7±8.8
HbA1c (mmol/mol) (%)	84.3±24.0 9.9±2.2
Diabetes duration (years)	14.0(7.5-21.0)
Taking insulin (%)	57.0

Table 2. 1-year outcomes (N=30)

Parameter	Baseline	1 year	Difference	P-value
Weight (kg)	120.8±27.8	104.9±28.7	-15.8±9.2	<0.001
BMI (kg/m2)	41.7±8.8	35.9±8.8	-5.8±3.4	<0.001
HbA1c (mmol/mol)	84.3±24.0	58.5±12.9	-25.9±24.3	<0.001
HbA1c (%)	9.9±2.2	7.5±1.2	-2.4±2.2	<0.001
Systolic blood pressure (mmHg)	136.4±14.9	123.9±15.8	-12.5±17.2	<0.001
ALT (U/l)	32.5±20.1	18.6±10.5	-13.9±18.2	<0.001
insulin daily dose (n=17)*	100(40-130)	30(0-62)	-70	0.003

*6 of the 17 (35%) patients discontinued insulin

2/30(6.7%) patients had early removal of Endobarrier: One was for gastrointestinal haemorrhage at 10 weeks having not complied with proton-pump-inhibitor advice. Nevertheless, during this limited time, he experienced 9.6 kg weight loss, his HbA1c fell from 109 to 47 mmol/mol (12 to 6.5%) and his insulin requirement fell from 140 to 30 Units daily. The other patient had early removal due to a hepatic abscess at 7 months. Additionally his abscess was drained and treated with intravenous antibiotics. During his implant, he achieved a weight loss of 18.4 Kg and his HbA1c changed from 55 to 54 mmol/mol (7.2 to 7.1%). Both patients made a full recovery.

93.8% of our patients stated that they would be extremely likely to recommend our service to friends and family.

Conclusion

Our data demonstrates Endobarrier as highly effective in patients with refractory diabesity. Maintenance of improvement after Endobarrier removal was achieved in 70%. There were high patient satisfaction levels and an acceptable safety profile. As endoscopy units are ubiquitous, our service could be readily disseminated.

Hepatic Abscess is a known risk as a result of Endobarrier treatment. Clinicians should be vigilant for this complication but if it occurs the device can, if necessary, be removed. 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.

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