Improvement in renal function in the first UK NHS EndoBarrier service for uncontrolled diabesity

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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.

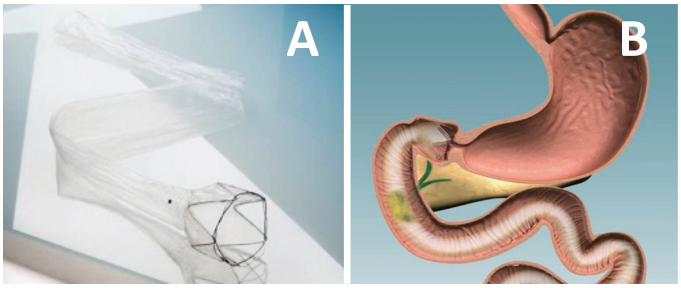

Fig. 1A. Photograph of EndoBarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIM

As the risk of progressive kidney disease is increased in individuals with a very high BMI, we assessed the impact of EndoBarrier on renal function in patients with advanced diabesity.

METHOD

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

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 (% Europid)	57.4
BMI (kg/m^2)	41.9±7.4
HbA1c (mmol/mol) (%)	80.2±22.5 9.5±2.1
*Diabetes duration (years)	12.0(8-19.5)
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^2)	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 had a significant impact on renal function:

Parameter	Baseline	At explant	Difference	P-value
Serum creatinine (µmol/L)	91.7±47.7	86.2±45.7	-5.5±15.4	0.007
eGFR (ml/min/1.73m^2)	84.3±25.2	90.1±26.4	5.8±10.7	<0.001

Table 4. Five patients had a raised serum creatinine (>133µmol/L) prior to Endobarrier; after implantation in four of these patients the creatinine reduced and in two creatinine normalised:

Patient	Creatinine at baseline (µmol/L)	Creatinine at explant (µmol/L)	Weight at baseline (kg)	Weight at explant (kg)	Weight loss (kg)	Comment
Patient 1	348	281	128.2	108.9	19.3	Big weight loss creatinine improved
Patient 2	284	329	131.2	124.6	6.6	Small weight loss creatinine deteriorated
Patient 3	166	152	122.4	98.8	23.6	Big weight loss creatinine improved
Patient 4	153	106	92.4	73	19.4	Big weight loss creatinine normalised
Patient 5	153	133	145.4	111	34.4	Big weight loss creatinine normalised

It was noteworthy (Table 4), that the four patients with renal impairment who sustained an improvement in kidney function had large weight loss (19.3-34.4kg), whereas in the patient without improvement in kidney function the weight loss was only 6.6 kg.

CONCLUSION

As previously documented, EndoBarrier resulted in considerable weight loss, improvement in glycaemic control, liver fat and 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. EndoBarrier was also associated with improvements in renal function and these observational findings warrant further investigation in a randomised controlled trial.

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