EndoBarrier treatment for longstanding type 2 diabetes and obesity: Outcomes one-year after EndoBarrier in 90 consecutively treated patients

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BACKGROUND

EndoBarrier (GI Dynamics, Boston, USA), is a 60 cm endoscopically implanted, impermeable intestinal liner which reduces weight and improves glycaemic control during a year of treatment in patients with type 2 diabetes and obesity.

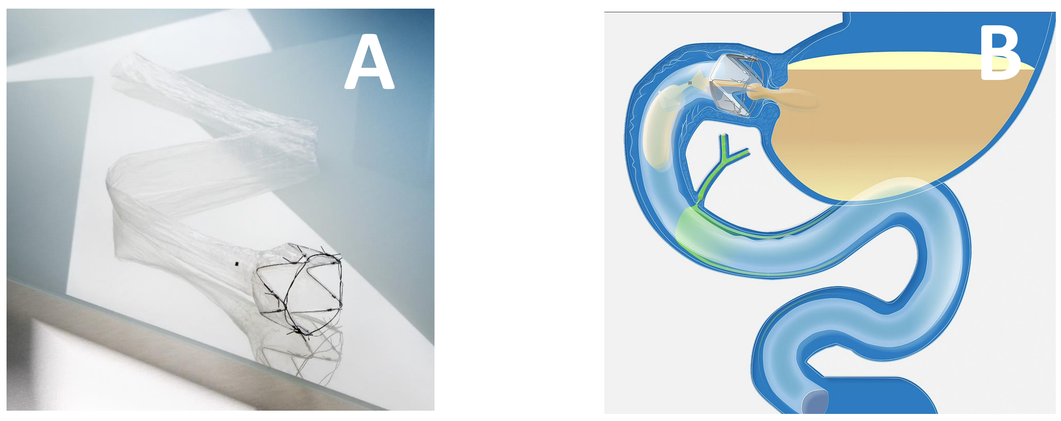


Fig. 1A. Photograph of EndoBarrier with anchor mechanism in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIMS and METHODS

We aimed to: i) assess the safety and efficacy of EndoBarrier in 90 consecutive patients with longstanding poorly controlled type 2 diabetes and obesity by monitoring outcomes in a registry; ii) assess maintenance of efficacy 12 months after EndoBarrier removal.

RESULTS

Table 1: All 90 patients have completed 12 months post EndoBarrier; 71/90 (79%) attended follow up. Baseline characteristics, n=71:

Parameter	N=71
Age (years)	51.3±5.6
Sex (% male)	46
Ethnicity (% white ethnicity)	52
BMI (kg/m^2)	41.1±6.5
HbA1c (mmol/mol) (%)	78.1±18.9 9.3±1.7
Diabetes duration (median (IQR) (years)	13.0 (7.0-17)
Taking insulin (%)	59

Table 2: Outcomes at explant of EndoBarrier; n=71

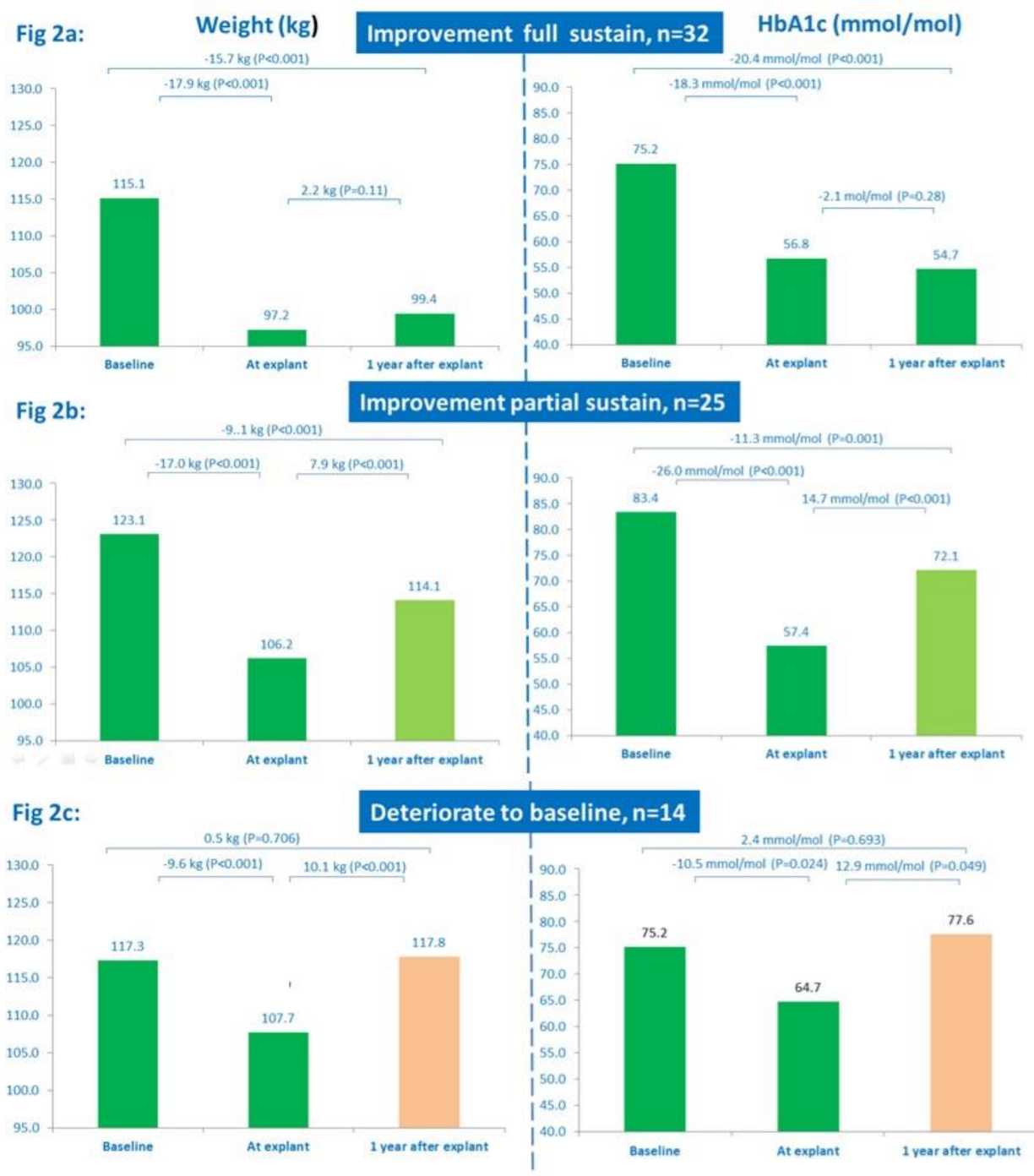
Parameter	Baseline	At explant	Difference	P-value
Weight (kg)	118.4±27.0	102.4±27.7	-15.9±8.6	<0.001
BMI (kg/m^2)	41.1±6.5	35.4±6.9	-5.7±3.2	<0.001
HbA1c (mmol/mol)	78.1±18.9	58.6±13.6	-19.5±18.4	<0.001
HbA1c (%)	9.3±1.7	7.5±1.2	-1.8±1.7	<0.001
Systolic blood pressure (mmHg)	139.0±15.0	126.6±17.6	-12.4±19.7	<0.001
Cholesterol (mmol/L)	4.84±1.19	4.01±0.96	-0.83±0.96	<0.001
ALT (U/l)	31.0±16.5	19.8±11.5	-11.2±18.4	<0.001
Insulin daily dose* (n=42)	98(53-163)	30(0-63)	-68	<0.001

*11 of the 42 (26.2%) patients discontinued insulin

Early removal of EndoBarrier: 13/90 (14%) patients had early EndoBarrier removal: five gastrointestinal haemorrhage, two liver abscess, one other abscess and five gastrointestinal symptoms. All made a full recovery after removal and most experienced benefit despite the adverse event. All other patients achieved a full year of EndoBarrier treatment.

One year post-EndoBarrier 32/71(45%) demonstrated fully-sustained improvement (which was defined as no significant difference between the weight and HbA1c at EndoBarrier removal and one year later – Figure 2a), 25/71(35%) partially-sustained improvement (they showed a significant deterioration in both weight and HbA1c between EndoBarrier removal and one year after removal but remained significantly improved in both weight and HbA1c compared to baseline – Figure 2b) and 14/71(20%) reverted to baseline (they showed no significant difference between baseline and one year after EndoBarrier removal – Figure 2c).

Figure 2: The weight and HbA1c at baseline, at explant and one year after explant in the 32/71 (45%) who fully maintained (Fig 2a), and 25/71 (35%) who partially maintained the improvement (Fig 2b). Also the 14/71 (20%) who deteriorated back to baseline (Fig 2c).



Of the 14/71 (20%) whose weight and/or HbA1c deteriorated (Figure 2c), 10/14 (71%) had depression or bereavement.

CONCLUSION

In patients with refractory diabesity, EndoBarrier resulted in considerable weight loss, improvement in glycaemic control, reduction in a marker of fatty liver (ALT) and reduction in the need for insulin. There continued to be significant improvement 12 months after removal in 80%. Patients with early removal because of serious adverse events made a full recovery and most derived considerable benefit despite the setback. These data are supportive of risk : benefit being strongly towards benefit and they support EndoBarrier as a potential important treatment option for longstanding poorly controlled type 2 diabetes and obesity. As endoscopy units are ubiquitous, delivery of EndoBarrier treatment could be relatively straightforward.