Comparing 9- vs 12-Month Implantation in the Worldwide EndoBarrier (EB) Registry

REJ RYDER[1], M YADAGIRI[1], L MUNRO[2], H FRYDENBERG[2], S FISHMAN[3], JP BYRNE[4], JP TEARE[5], C DE JONGE[6], JW GREVE[7], JJ MCMASTER[8], J CHISHOLM[9], L KOW[9], JC MASON[10], J STEIN[11], RV COHEN[12], P SEN GUPTA[1,5]

[1]Birmingham, UK, [2]Richmond, Australia, [3]Tel Aviv, Israel, [4]Southampton, UK, [5]London, UK, [6]Eindhoven, Netherlands, [7]Heerlen, Netherlands, [8]Brisbane, Australia, [9]Adelaide, Australia, [10]Manchester, UK, [11]Frankfurt, Germany, [7]Niesky, Germany, [12]São Paulo, Brazil

ABSTRACT

Uncertainty exists re risk:benefit of proximal intestinal exclusion with EB, a novel endoscopic duodenal jejunal liner device for obesity, both with and without diabetes. In view of this, during 2017, an independent, secure, on line registry was established under the auspices of the Association of British Clinical Diabetologists, for the collection of safety and efficacy data worldwide. As of May 2023, data had been entered on 1068 patients, of whom 196 (age 51.7±10.4 years, 48% male, 81% white ethnicity, BMI 40.0±7.2kg/m^2) had both 9- and 12-month data entered. EB had considerable impact on weight and HbA1c (Table). There was no difference between the mean±SD reduction in HbA1c or weight at 9- vs 12-months (HbA1c: 1.49±1.54% vs 1.55±1.54% (p=0.221); weight: 11.9±8.1kg vs 12.6±8.1kg (p=0.064). The higher the HbA1c the greater the fall but again no difference between 9- and 12-months (Table 2). In the full registry, 45/1068 (4.2%) experienced serious adverse events (SAE). 15/45 (33.3%) SAE would have been avoided by removal at 9-months (9 liver abscess, 5 GI bleed, one cholecystitis). It was particularly noteworthy that 9/14 (64.3%) liver abscess SAEs would have been avoided by removal at 9-months. This international data from the EB registry suggests that the benefits of EB are achieved in 9-months and a reduction in the recommended implantation period from 12- to 9-months would reduce SAEs, especially the liver abscess SAE.

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[1,2]. Many of the serious adverse events (SAE) associated with EndoBarrier occur during the last three months of treatment and reducing the period of implantation to 9-months may reduce the complication rate[3].

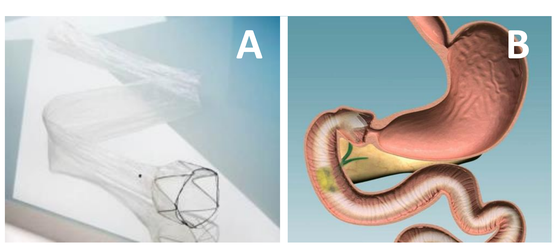

Fig. 1A. Photograph of Endobarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIM

In view of uncertainty about risks versus benefits of EndoBarrier, during 2017, an independent, secure, on-line registry was established under the auspices of the Association of British Clinical Diabetologists (ABCD), for the collection of safety and efficacy data of EndoBarrier treated patients worldwide. We aimed to assess safety and efficacy for 9-months vs 12-months implantation using data in the registry.

METHOD

We invited EndoBarrier users from centres worldwide to register to enter the before and after data from their EndoBarrier treated patients into the registry.

RESULTS

As of May 2023, data had been entered on 1068 EndoBarrier treated patients (from 35 centres in 10 countries), of whom 196 (12 centres in 6 countries: Australia, Brazil, Germany, Israel, Netherlands and United Kingdom) had both 9- and 12-month data entered.

Table 1: Baseline demographics of the 196 patients with both 9- and 12-month data

Parameter	n=196
Age (years)	51.7±10.4
Sex (% male)	48
Ethnicity (% white)	81
BMI (kg/m^2)	40.0±7.2

Fall in HbA1c

The fall in HbAc1 was affected by the fact that 13.5% of the 1069 patients did not have diabetes, and in many of those with diabetes the glycaemic control was good. Analysis of the data according to baseline HbA1c was therefore undertaken as shown in Table 2.

SUMMARY

It is well established that EndoBarrier as highly effective in people with longstanding poorly controlled type 2 diabetes and obesity[1] and that that the effects of EndoBarrier therapy on glycaemic control, weight, blood pressure and cholesterol are likely to reduce the complications of diabetes[1,3,4]. We show here that reducing the implantation period from 12-months to 9-months would have resulted in no significant difference in weight loss or in the improvement in HbA1c, but would have led to a 33.3% reduction in SAE. It was particularly noteworthy that 64.3% liver abscess SAE would have been avoided by removal at 9-months. These data support a change in the recommended implantation period for EndoBarrier from 12-months to 9-months..

Table 2. Impact of EndoBarrier on weight and HbA1c. The higher the initial HbA1c, the greater the reduction. There was no difference between the reduction in weight or HbA1c at 9-months compared to 12-months. The higher the HbA1c the greater the fall but again no difference between 9- and 12-months.

Parameter	n	Baseline	9-months	12-months	Difference 9-months vs baseline	Difference 12-months vs baseline	P-value baseline vs 9-months	P-value baseline vs 12-months	P-value difference 9- vs 12-months
Weight (kg)	171	114.9±22.9	102.9±22.4	102.2±23.0	-11.9±8.1	-12.6±8.1	<0.001	<0.001	0.06
All HbA1c (%)	144	8.9±1.7	7.4±1.2	7.3±1.2	-1.5±1.5	-1.6±1.5	<0.001	<0.001	0.22
HbA1c ≥ 7%	129	9.2±1.5	7.5±1.2	7.4±1.1	-1.7±1.5	-1.7±1.5	<0.001	<0.001	0.23
HbA1c ≥ 8%	99	9.6±1.4	7.7±1.3	7.6±1.2	-2.0±1.6	-2.0±1.5	<0.001	<0.001	0.22
HbA1c ≥ 9%	59	10.5±1.2	7.8±1.6	7.7±1.4	-2.6±1.7	-2.7±1.5	<0.001	<0.001	0.27
HbA1c ≥ 10%	37	11.2±0.9	8.2±1.6	8.0±1.4	-3.0±1.7	-3.2±1.4	<0.001	<0.001	0.08

Serious adverse events

Table 3. In the full registry, 45/1068 (4.2%) experienced serious adverse events (SAE). All patients with SAE made a full recovery, and most experienced benefits despite the SAE. 15/45 (33.3%) SAE would have been avoided by removal at 9-months (9 liver abscess, 5 GI bleed, one cholecystitis). It was particularly noteworthy that 9/14 (64.3%) liver abscess SAEs would have been avoided by removal at 9-months. (GI = gastrointestinal)

Serious Adverse Event	All	Before 9-months	After 9-months
Early removal because of GI bleed	25	20	5
Liver abscess (early removal = 9/12; found at time of routine explant = 3/12)	12	5	7
Liver abscess after prolonged implant (1/2 = nearly 2 years; 1/2 = 16 months)	2	0	2
Early removal because of pancreatitis	2	2	0
Early removal because of cholecystitis	2	1	1
Early removal because of liner obstruction - surgical removal required*	1	1	0
Abdominal abscess due to small perforation of bowel in relation to EndoBarrier	1	1	0
Total	45	30	15

*Extraction hood came off during removal and EndoBarrier became stuck in the oesophagus requiring removal through a small incision in the side of the neck

CONCLUSION

This international data from the EndoBarrier worldwide registry suggests that the benefits of EndoBarrier are achieved in 9-months and a reduction in the recommended implantation period from 12- to 9-months would reduce SAE, especially the liver abscess SAE..

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