

R.E.J. Ryder¹, R. Drummond², B. McGowan³, S Amiel⁴, R. Lopez-Gonzalez⁵, J. Pujol⁵, H. Frydenberg⁶, J. Stein⁷, T. Battelino⁸, S. Fishman⁹, C. de Jonge¹⁰, J. Greve¹¹, R. Cohen¹⁰, P. M. Yadagiri¹, Sen Gupta^{11,1}

¹City Hospital, Birmingham, UK, ²Glasgow Royal Infirmary, Glasgow, UK, ³Guy's and St Thomas' Hospitals, London, UK, ⁴Kings College Hospital NHS Foundation Trust, London, UK, ⁵Consors Sanitari Integral, Barcelona, Spain, ⁶Epworth Centre for Bariatric Surgery, Richmond, Australia, ⁷Frankfurt-Sachsenhausen, Frankfurt, Germany, ⁸University Medical Center Ljubljana, Ljubljana, Slovenia, ⁹Tel Aviv Sourasky Medical, Tel Aviv, Israel, ¹⁰Maastricht University Medical Center, General Surgery, Netherlands, ¹¹Zuyderland MC, Heerlen, Netherlands, ¹²Oswaldo Cruz Hospital, Sao Paulo, Brazil.

BACKGROUND

Duodenal jejunal bypass liner (DJBL) also known as EndoBarrier® or RESET ® (Morphic Medical, Boston, USA), 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). It is held in place by a nitinol anchor, such that food passes through it without coming into contact with the small intestine, thereby interfering with the normal digestive processes that occur in this region¹. The endoscopic insertion and removal of EndoBarrier are day case procedures, performed in less than an hour under general anaesthesia or heavy sedation. This form of reversible bariatric procedure has been shown to reduce weight and improve glycaemic control in patients with diabetes and obesity^{1,2}. As DJBL has been most commonly called EndoBarrier we will call it that here.

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 rate³.

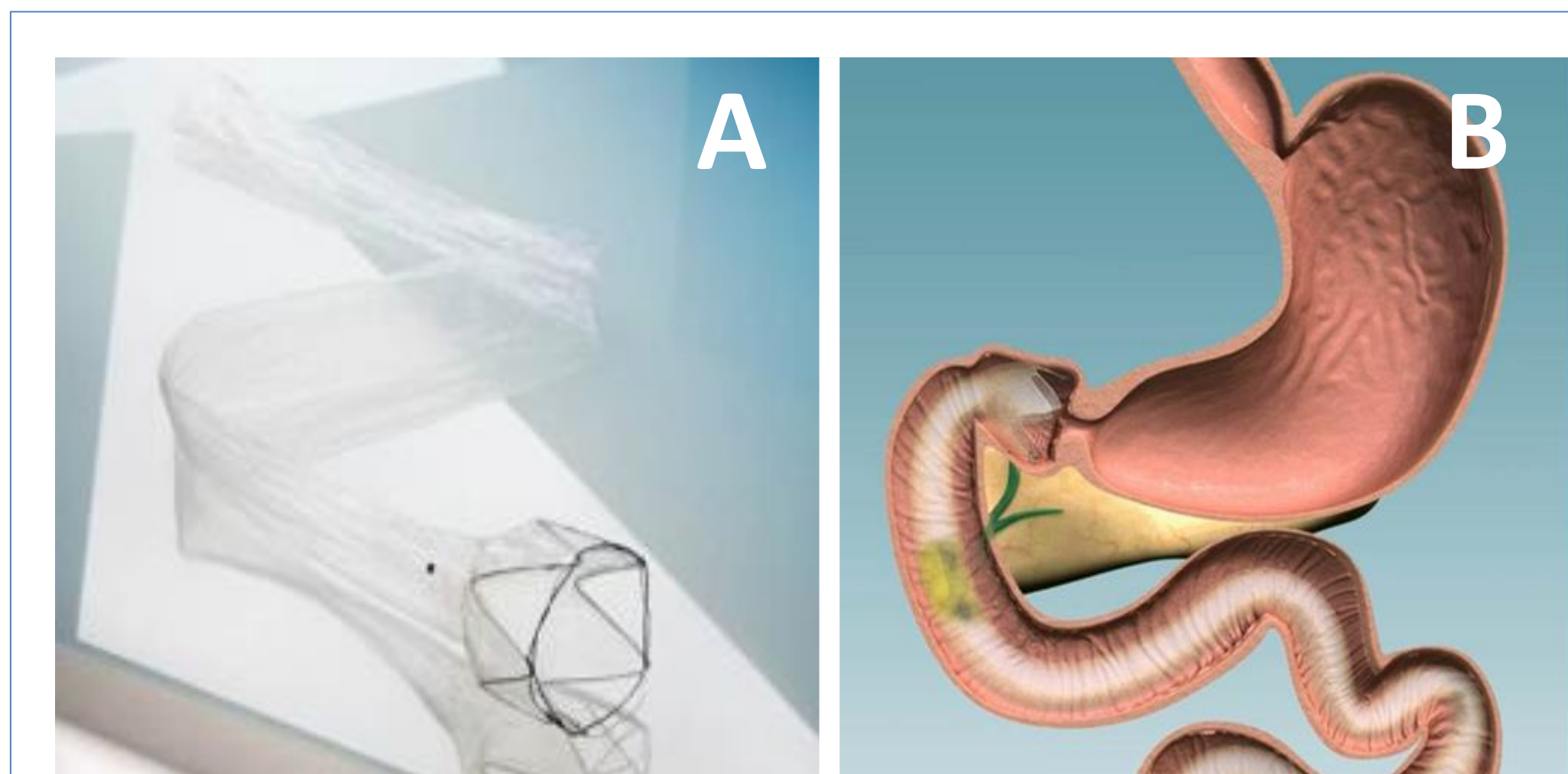


Fig. 1A. Photograph of EndoBarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

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 June 2025, data had been entered on 1298 EndoBarrier treated patients (from 37 centres in 12 countries), of whom 258 (19 centres in 9 countries: Australia, Brazil, Germany, Israel, Netherlands, Scotland, Slovenia, Spain and England) had both 9- and 12-month data entered.

Parameter	n=258
Age (years)	49.5±13.3
Sex (% male)	46.5
Ethnicity (% white)	83
BMI (kg/m ²)	39.6±6.9

Table 1: Baseline demographics of the 258 patients with both 9- and 12-month data

Fall in HbA1c

The fall in HbA1c was affected by the fact that 23% of the 1298 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 obesity¹ and 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 little difference in weight loss or in the improvement in HbA1c, but would have led to a 36.7% reduction in SAE. It was particularly noteworthy that 66.6% 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 little 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)	228	113.8±22.5	101.6±22.0	100.7±23.0	-12.2±8.1	-13.1±8.6	<0.001	<0.001	0.005
All HbA1c (%)	197	8.8±2.0	7.3±1.4	7.3±1.3	-1.5±1.7	-1.5±1.7	<0.001	<0.001	0.571
HbA1c ≥ 7%	170	9.3±1.8	7.5±1.3	7.5±1.2	-1.7±1.7	-1.7±1.8	<0.001	<0.001	0.639
HbA1c ≥ 8%	132	9.8±1.7	7.7±1.4	7.7±1.3	-2.0±1.8	-2.1±1.8	<0.001	<0.001	0.447
HbA1c ≥ 9%	82	10.6±1.7	7.9±1.6	7.8±1.5	-2.6±2.0	-2.8±1.9	<0.001	<0.001	0.203
HbA1c ≥ 10%	48	11.4±1.7	8.4±1.8	8.1±1.5	-3.1±2.3	-3.3±2.0	<0.001	<0.001	0.091
HbA1c ≥ 11%	26	12.4±1.9	8.6±2.0	8.5±1.8	-3.8±2.7	-3.8±2.5	<0.001	<0.001	0.857

Serious adverse events

Table 3. In the full registry, 60/1298 (4.6%) experienced serious adverse events (SAE). All patients with SAE made a full recovery, and most experienced benefits despite the SAE. 22/60 (36.7%) SAE would have been avoided by removal at 9-months (12 liver abscess, 5 GI bleed, one cholecystitis and surgical removal required as liner was displaced). It was particularly noteworthy that 12/18 (66.6%) 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 (removal: by endoscopy = 30/31; by laparoscopy = 1/31)	31	26	5
Liver abscess (early removal = 12/15; found at time of routine explant = 3/15)	15	6	9
Early removal because of pancreatitis or cholecystitis	4	3	1
GI bleed after prolonged implant (1/3 = 18 months; 2/3 = 13 months)	3	0	3
Liver abscess after prolonged implant (1/2 = nearly 2 years; 1/2 = 16 months)	3	0	3
Early removal because of liner obstruction - surgical removal required*	1	1	0
Abdominal abscess due to small perforation of bowel in relation to DJBL	1	1	0
Early removal - gastric perforation – surgical removal as part of successful Roux-en-Y procedure	1	1	0
Surgical removal required as liner was displaced	1	0	1
Total	60	38	22

*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..

REFERENCES

1. Ryder, REJ et al. Br J Diabetes 2019;19:110-117
2. Jirapinyo, P et al. Diabetes Care 2018;41(5):1106-1115
3. Ryder, REJ et al. Diabetes Care 2023;46:e89–e91
4. Ryder, REJ et al. Br J Diabetes 2022;22:82–86