

Benefits and Risks in 1101 Duodenal-Jejunal Bypass Liner (DJBL) Treated Patients



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ABSTRACT
 DJBL (aka EndoBarrier® and RESET®) is a novel endoscopic duodenal jejunal liner device for obesity, both with and without diabetes. In view of uncertainty re risk vs benefit, during 2017, an independent, secure, online registry was established under the auspices of the Association of British Clinical Diabetologists, for the collection of safety and efficacy data worldwide. As of January 2024, data had been entered on 1101 patients {age 51.3 ± 11.3 years, 52% male, 84% diabetes, BMI 40.9 ± 8.8 kg/m²} and showed many benefits (Tables 2 & 3). There were 47 (4.3%) SAEs and 146 (13.3%) less serious AEs (Table 4). All SAE patients made a full recovery and most derived significant benefit. The benefits of DJBL therapy are likely to reduce the complications of diabetes. This international data from the DJBL registry suggests that the likely benefits far outweigh the risks.

BACKGROUND
 The Duodenal-Jejunal Bypass Liner (DJBL), also known as EndoBarrier® and 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}.

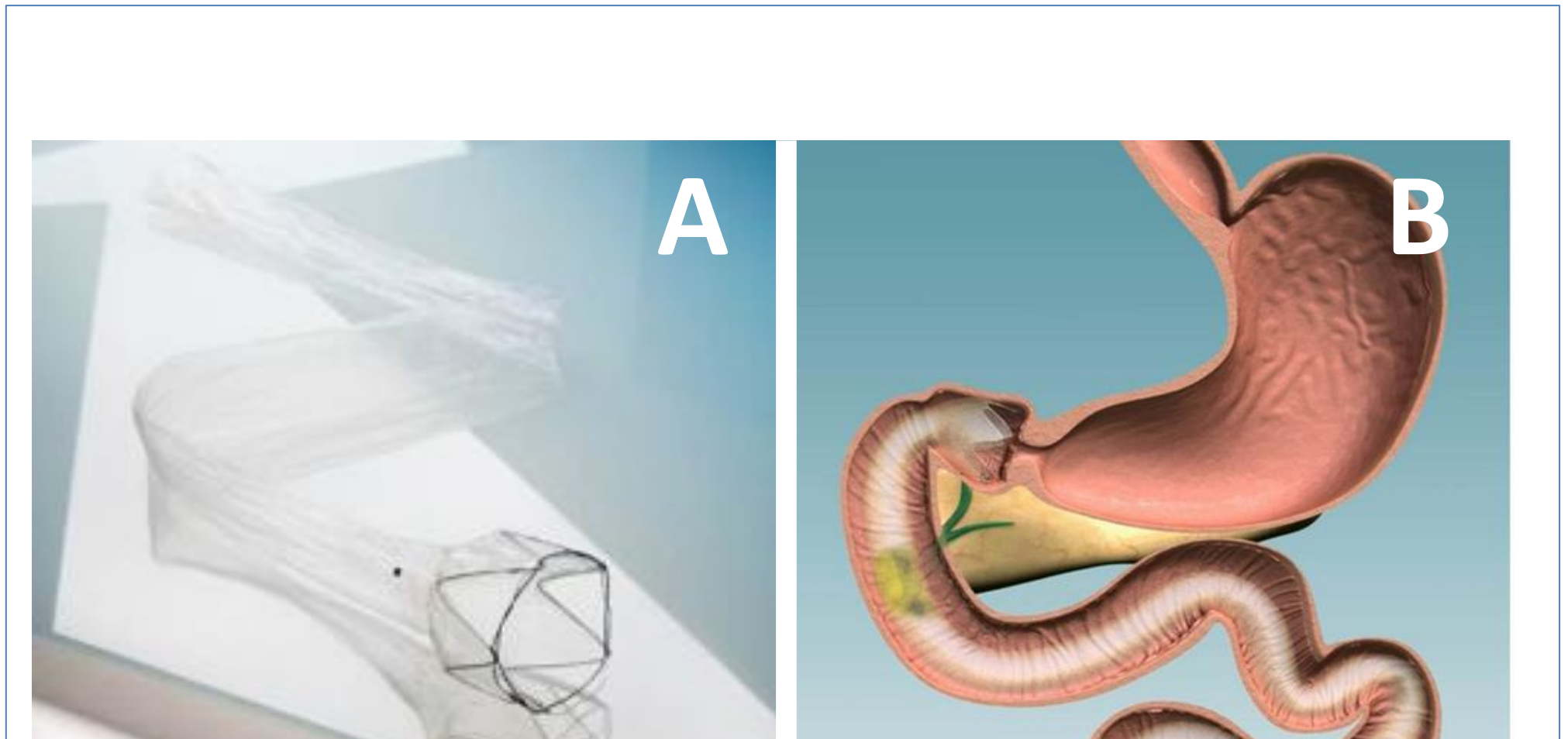


Fig. 1A. Photograph of DJBL with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

AIM
 Nevertheless, uncertainty exists about risks versus benefits of DJBL. In view of this, during 2017, an independent, secure, online registry was established under the auspices of the Association of British Clinical Diabetologists (ABCD), for the collection of safety and efficacy data of DJBL treated patients worldwide.

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

RESULTS
 As of January 2024, data had been entered on 1101 DJBL treated patients from 36 centres in 11 countries: Australia, Austria, Brazil, Czech Republic, England, Germany, Israel, Netherlands, Scotland, Slovenia and Spain. The demographics of these patients are shown in Table 1.

Table 1: Baseline demographics of the 1101 patients

Parameter	n=1101
Age (years)	51.3±11.3
Sex (% male)	52
BMI (kg/m ²)	40.9±8.8
Diabetes (%)	84

DJBL led to many benefits, including: in those with both baseline and explant (i.e. at removal) data, considerable improvements in weight, HbA1c, Systolic blood pressure and cholesterol as shown in table 2.

Table 2: Changes in weight, HbA1c, Systolic BP and cholesterol.

Parameter	n	Baseline	At removal	Difference	P-value
Weight (kg)	888	119.4±25.6	105.9±24.2	-13.6±9.8	<0.001
HbA1c (%)	710	8.4±1.9	7.1±1.3	-1.3±1.6	<0.001
Systolic BP (mmHg)	448	135.7±18.0	129.5±17.0	-6.3±19.2	<0.001
Cholesterol (mmol/L)	467	4.8±1.2	4.2±1.0	-0.6±1.0	<0.001

Fall in HbA1c
 The fall in HbA1c found in the whole group was affected by the fact that 16% of the 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 is shown in Table 3 and this data clearly shows that the higher the baseline HbA1c the greater the impact of DJBL treatment.

SUMMARY
 In this analysis from the worldwide DJBL registry, the mean weight loss during the period of EndoBarrier implantation was 13.3 kg with associated improvements in glycaemic control blood pressure and cholesterol. The higher the baseline HbA1c the greater the fall in HbA1c with a mean fall of 3.8% with those with a baseline HbA1c ≥ 11%. The rate of serious adverse events was 4.3% with the majority of these (2.4%) being gastrointestinal bleeds. The rate of early removal for hepatic abscess (1.1%) was noticeably less than that the 3.5% rate found in the US pivotal trial². All patients with a serious adverse event made a full recovery and most experienced considerable benefit from the treatment despite the adverse event.

Table 3: HbA1c response to DJBL according to baseline HbA1c - the higher the initial HbA1c, the greater the fall.

HbA1c Range (%)	n	Baseline	At removal	Difference	P-value
All HbA1c	710	8.4±1.9	7.1±1.3	-1.3±1.6	<0.001
All HbA1c ≥ 7	562	9.0±1.6	7.4±1.2	-1.6±1.6	<0.001
All HbA1c ≥ 8	410	9.6±1.5	7.7±1.3	-1.9±1.7	<0.001
All HbA1c ≥ 9	236	10.4±1.4	7.9±1.4	-2.5±1.8	<0.001
HbA1c ≥ 10	127	11.3±1.4	8.1±1.5	-3.2±1.9	<0.001
HbA1c ≥ 11	62	12.2±1.6	8.3±1.7	-3.8±2.2	<0.001

Serious Adverse Events
 There were 47 (4.3%) serious adverse events and 146 (13.3%) less serious adverse events (Table 4). All serious adverse event patients made a full recovery and most derived significant benefit despite the event. Some serious adverse events could have been avoided if patients had adhered to guidelines (for examples see reference 1).

Table 4. Serious adverse events in 1101 DJBL treated patients (GI = gastrointestinal).

Serious Adverse Event	n	%
Early removal because of gastrointestinal bleed (removal: by endoscopy = 25/26; by laparoscopy = 1/26)	26	2.4
Liver abscess (early removal = 9/12; found at time of routine explant = 3/12)	12	1.1
Early removal because of pancreatitis or cholecystitis	4	0.4
Liver abscess after prolonged implant (1/2 = nearly 2 years; 1/2 = 16 months)	2	0.2
Early removal because of liner obstruction - surgical removal required*	1	0.1
Abdominal abscess due to small perforation of bowel in relation to DJBL	1	0.1
Early removal because of gastric perforation - surgical removal as part of successful Roux-en-Y procedure	1	0.1
Total	47	4.3

Less Serious Adverse Event	n	%
Early removal because of gastrointestinal symptoms or migration or liner obstruction	81	7.4
Precautionary hospitalisation (gastrointestinal symptoms, difficult removal) or endoscopy	65	5.9
Total	146	13.3

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

CONCLUSION
 The effects of DJBL therapy on glycaemic control, weight blood pressure and cholesterol are likely to reduce the complications of diabetes. This international data from the DJBL worldwide registry suggests that the likely benefits of DJBL treatment, far outweigh the risks. It is noteworthy that the benefits of DJBL have been shown to be durable over 4 years³. The benefits to the people with diabetes concerned are most readily appreciated from pictorial examples and from interviews with them⁴.

REFERENCES
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