

Benefits of reducing duration of endoscopic duodenal-jejunal bypass liner implantation to nine months in treatment of diabetes

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Abstract

Aims: To assess the safety and efficacy of duodenal-jejunal bypass liner (DJBL) implantation for 9 months or 12 months in patients with obesity and sub-optimally controlled type 2 diabetes (T2DM).

Methods: Over 4.25 years DJBLs were implanted in 90 adult patients with obesity and sub-optimally controlled T2DM at a single centre in England. The liners remained *in situ* for up to 12 months and outcomes were monitored in a registry.

Results: Of the 90 patients (BMI $41.5 \pm 7.1 \text{ kg/m}^2$, HbA_{1c} $79.3 \pm 20 \text{ mmol/mol}$), 53% were insulin-treated. During DJBL treatment, there was no difference between the mean \pm SD fall in HbA_{1c} at 9 months ($20.5 \pm 18.8 \text{ mmol/mol}$) vs. 12 months ($20.5 \pm 19.4 \text{ mmol/mol}$) ($p=0.95$). The mean \pm SD weight loss at 9 months ($13.8 \pm 7.7 \text{ kg}$) was $1.6 \pm 3.6 \text{ kg}$ less than that at 12 months ($15.4 \pm 8.4 \text{ kg}$) ($p < 0.001$). By 12 months, 15.6% of patients had had early DJBL removal due to serious adverse events (SAEs), from which they all recovered. Of these SAEs, 43% would have been avoided by DJBL removal at 9 months.

Conclusion: DJBL is effective in people with intractable diabetes. To reduce the incidence of SAEs, our data support reducing the recommended/conventional implantation period for DJBL from 12 months to 9 months.

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Key words: DJBL, duodenal-jejunal bypass liner, diabetes, type 2 diabetes, obesity, EndoBarrier®, RESET®

Background

The increasing incidence of diabetes – type 2 diabetes with obesity – is an international issue.¹ The role of obesity in the aetiology and pathogenesis of type 2 diabetes (T2DM) is well

documented,²⁻⁴ as is the importance of optimal metabolic control. Good glycaemic control, which is essential to reduce the risk of microvascular and macrovascular complications,⁵⁻⁸ is notoriously difficult to achieve.⁹ First-line strategies of dietary and lifestyle interventions to reduce obesity are also effective in improving glycaemic control but are generally challenging for patients to implement and maintain.¹⁰ Until the recent advent of agents that target the entero-insular axis, pharmacological interventions have generally offered limited efficacy with unacceptable risk-benefit profiles.¹¹ Bariatric surgery has been shown to offer immediate improvement in glycaemia with control improving as weight loss occurs,¹² leading international diabetes organisations to recommend that metabolic surgery be used more often in the treatment of T2DM with obesity.¹³ Roux-en-Y gastric bypass (RYGB) is particularly effective in the treatment of diabetes, but is highly invasive and irreversible.¹⁴ The duodenal-jejunal bypass liner (DJBL) – also known as EndoBarrier® – was developed to mimic the small bowel actions of RYGB whilst being less invasive and reversible, and studies have shown DJBL to improve glycaemic control and reduce weight in people with diabetes.¹⁴⁻²³

In July 2023 GI Dynamics (Boston, USA) announced its rebrand to Morpheic Medical Inc. (Boston, USA) and the re-naming of its product EndoBarrier® to RESET®. This is the only DJBL that has ever had approval for clinical use (Figure 1). This 60-cm fluoropolymer liner is implanted and removed endoscopically under general anaesthesia. The procedure can be viewed online.²⁴ The liner, which is currently recommended to be *in situ* for 12 months, is anchored at the duodenal bulb, allowing nutrients to pass directly from the stomach into the jejunum.^{14,16,24} To assess the potential utility of this approach, City Hospital in Birmingham, UK, provided DJBL treatment to people with diabetes who were unable to achieve adequate glycaemic control despite intensive anti-diabetes medical therapy. During the treatment period, and after DJBL removal, patient data were recorded in the ABCD international DJBL registry.^{15,17,18,25-28}

Worldwide, the serious adverse event (SAE) rate for DJBL is 4.2%, with all patients making a full recovery and most experiencing DJBL related-benefit despite the SAE.²⁹ It has been suggested that reducing the period of DJBL implantation to nine months may reduce the complication rate.²⁹ The current

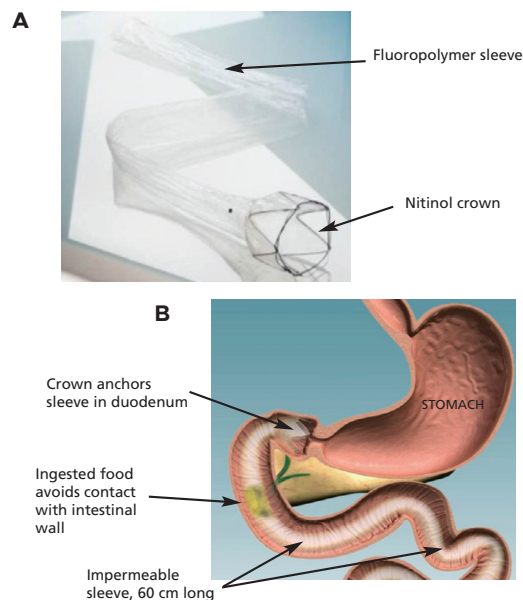
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Figure 1. (A) The duodenal jejunal bypass liner (DJBL) and (B) a diagram of the device in situ



Adapted from <https://abcd.care/endobarrier-studies>

interrogation of the Birmingham EndoBarrier-treated patients in the ABCD international DJBL registry aimed to compare the safety and efficacy of DJBL following 9 months' vs. 12 months' implantation.

Methods

Patients were engaged in a comprehensive two-year pathway for diabetes management at the Diabetes Centre at City Hospital in Birmingham, UK, as described previously.^{15,25} People with diabetes who were unable to achieve adequate glycaemic control despite intensive anti-diabetes medical therapy were provided DJBL treatment. Patients were informed of the requirements of the insertion and removal procedures,^{15,24} and initial post-procedure eating behaviours, plus the need to take proton pump inhibitors (omeprazole 40 mg twice daily) and a daily multivitamin preparation throughout the period of DJBL implantation. During the treatment period and after DJBL removal body weight and parameters of metabolic control, including glycaemia, were monitored and recorded in the ABCD international DJBL registry.^{15,17,25-28}

Between July 2013 and November 2017, DJBLs were implanted into 90 people (aged 28-70 years) with sub-optimally controlled T2DM with obesity (BMI >30 kg/m²) and outcomes were recorded in the registry.²⁵ Of these 90 patients 28 were in research studies (REVISE-Diabetes trial (n=20): ISRCTN00151053; End-OSA trial (n=8): ISRCTN33788132) and 62 in an NHS service.¹⁵ By November 2018 all devices had been removed and outcomes during the period of implantation and during the year following removal have been reported.^{15,25}

Table 1. Baseline characteristics of 78 people with diabetes who attended review at both 9-months and 12-months after DJBL implantation.

Parameter	n=78
Age (years)	51.3±8.4
Sex (% male)	49
Ethnicity (% white ethnicity)	59
BMI (kg/m ²)	41.5±7.1
HbA _{1c} (mmol/mol) (%)	79.3±20.1 (9.4±1.8)
Diabetes duration (median (iQR) (years))	11.0 (7.0-17.2)
Taking insulin (%)	54
Taking GLP-1 RA (%)	67
Taking GLP1 RA and insulin (%)	32

GLP-1 RA = GLP-1 receptor agonist

Results

Baseline data for the 87% of patients who attended review at both 9 months and 12 months after DJBL implantation are shown in Table 1. Compared to baseline DJBL significantly improved glycaemic control and weight loss, but the longer period of implantation was only associated with a further weight reduction of 1.6kg (p<0.0001) (Table 2). By one year, 15.6% patients had required early DJBL removal for SAEs (Table 3). All made a full recovery, and most experienced benefit despite the SAE/complication. As shown in table 3, 43% of these SAEs would have been avoided by DJBL removal at nine months.

Discussion

It has long been recognised that it is more difficult for people with T2DM than their non-diabetic counterparts to lose weight,³⁰ and this is especially the case in insulin-treated patients with obesity and sub-optimal glycaemic control.²⁷ Adequate glycaemic control is still not achievable by many patients with diabetes despite intensive education and pharmacological interventions, even with the GLP-1 receptor agonists and SGLT2 inhibitors which facilitate weight loss. Newer incretin-based therapies such as tirzepatide appear to offer increased weight loss, improved glycaemic control and additional health benefits,³¹ and these agents are likely to be used before turning to more invasive procedures.

RYGB is an effective invasive option in this situation,^{13,14} but is not without short- and longer-term complications.³² The mechanisms of action of DJBL, although not fully understood, are thought to be similar to those of the foregut hypothesis mechanisms of RYGB.¹⁴ Dumping syndrome occurs in about 85% of people who have undergone RYGB,³² but was not reported by our DJBL-treated people with diabetes. RYGB and DJBL may be mechanistically similar, but the latter is reversible and considerably less expensive.

An hepatic abscess rate of 3.2% resulted in early termination, in 2016, of the ENDO Trial,^{23,33} – the first DJBL

Table 2. During DJBL treatment, there was no difference between the fall in HbA_{1c} at 9-months vs 12-months (p=0.95). The weight loss at 9-months was 1.6 kg less than that at 12-months (p<0.001).

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)	78	120.0±26.8	106.3±27.7	104.6±27.9	-13.8±7.7	-15.4±8.4	<0.001	<0.001	<0.001
HbA _{1c} (mmol/mol)	78	79.3±20.1	58.9±14.7	58.8±13.2	-20.5±18.8	-20.5±19.4	<0.001	<0.001	0.95
HbA _{1c} (%)	78	9.4±1.8	7.5±1.3	7.5±1.2	-1.9±1.7	-1.9±1.8	<0.001	<0.001	0.95

Table 3. Serious adverse events (SAE) leading to early removal of DJBL.

Serious adverse event	All	Before 9-months	After 9-months
Early removal because of gastrointestinal haemorrhage	5	5	0
Early removal because of liver abscess	2	1	1
Early removal because of gastrointestinal symptoms - Endobarrier had migrated	2	1	1
Early removal because of gastrointestinal symptoms	2	0	2
Early removal because of cholecystitis	1	0	1
Abdominal abscess due to small perforation of bowel in relation to EndoBarrier	1	1	0
Early removal because of liner obstruction and gastrointestinal symptoms	1	0	1
Total	14	8	6

pivotal trial for the United States Food and Drug Administration. The ABCD international DJBL registry has only recorded an incidence of 1.1%, however.^{14,23,29} The new US FDA pivotal study (Rev F) (STEP-1) is including antibiotic cover at DJBL insertion and extraction and daily temperature monitoring for early detection of hepatic abscess and is expected to report in December 2027.³⁴ It was assumed that this safety issue and reports of device-induced tears led to the suspension of the CE Mark for the DJBL in 2017,^{26,35} but the loss of the CE Mark in November 2017 was reported to be due to non-conformity to medical device quality management system standards.³⁶ Restoration of the CE Mark, granting use in the UK and EU, is anticipated in 2024.³⁷

Endoscopy units are widely available in healthcare systems, thus making it relatively easy to incorporate a DJBL service. DJBL offers a relatively less invasive opportunity that is fully reversible compared to metabolic/bariatric surgery to treat refractory diabetes despite intensive pharmacological therapy. As noted previously, DJBL treatment for 9 (and 12) months reduces body weight, improving glycaemic control, blood pressure, cholesterol and associated metabolic biomarkers,^{27,29,35} which in turn reduces the incidence and progression of diabetes complications – notably microvascular and macrovascular sequelae.^{5-8,15}



Key messages

- ▲ In people with intractable diabetes, we previously demonstrated that endoscopic duodenal-jejunal bypass liner (DJBL) treatment led to a considerable improvement in weight and microvascular risk, through improved BP and glycaemic control and a significant reduction in cardiovascular risk as assessed by the UKPDS risk engine.
- ▲ We have also previously demonstrated that 3-years following removal of DJBL, 77% of people with diabetes maintained most of the improvement achieved during a year of DJBL treatment.
- ▲ The data presented here suggests that most of the benefits of DJBL are achieved during the first 9 months and that reducing the recommended treatment time from 12- to 9-months could reduce the SAEs by 43%, without much loss of benefit.

DJBL treatment reduced insulin requirements and 37% of patients were able to discontinue insulin therapy, but of particular interest is that the benefits of DJBL are maintained three years after removal in 77% of patients.²⁷ Examples of individual patient-perceived benefits of DJBL can be viewed online.³⁸ DJBL offers benefits, but it is necessary to consider associated risks of treatment, notably liver abscess, and gastrointestinal issues such as bleeding and obstruction. Recent data from the ABCD international DJBL registry corroborate our observations that DJBL removal at nine months enhances the safety profile of this treatment.³⁹

In conclusion, our data support a change in the recommended implantation period for DJBL from 12 months to 9 months. As endoscopy units are ubiquitous, delivery of DJBL treatment could be easily scalable.



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Conflict of interest REJR has received speaker fees, and/or consultancy fees and/or educational sponsorships from Abbott, AstraZeneca, Besins, BioQuest, Morphic Medical and Novo Nordisk. PSG has received support from Novo Nordisk for speaker/organising course/educational event.

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