# Duodenal Jejunal Bypass Liner (Djbl) Treatment For Type 2 Diabetes And Obesity: Comparison Between 9- And 12 Months Implantation Using Data From A Worldwide Registry

R.E.J. Ryder[1], R. Lopez-Gonzalez[2], C. Lazzara[2], J.P. Gebelli[2], L. Munro[3], H. Frydenberg[3], J. Stein[4], T. Battelino[5], S. Fishman[6], J. Bryne[7], C. de Jonge[8], J. Greve[9], R. Cohen[10], P. M. Yadagiri[1], Sen Gupta[11,1]

[1]City Hospital, Birmingham, UK, [2]Belivitge University Hospital, Barcelona, Spain, [3]Epworth Hospital, Richmond, Australia, [4]Krankenhaus Sachsenhausen, Frankfurt, Germany, [5]University Medical Center, Ljubljana, Slovenia, [6]Sourasky Medical, Tel Aviv, Israel, [7]University Hospital Southampton NHS Foundation Trust, Southampton, UK, [8]Maastricht University Medical Center, General Surgery, Netherlands, [9]Zuyderland MC, Heerlen, Netherlands, [10]Oswaldo Cruz Hospital, Sao Paulo, Brazil, [11]Guy's and St Thomas' Hospitals, London, UK.

## 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 region[1]. 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 rate[3].

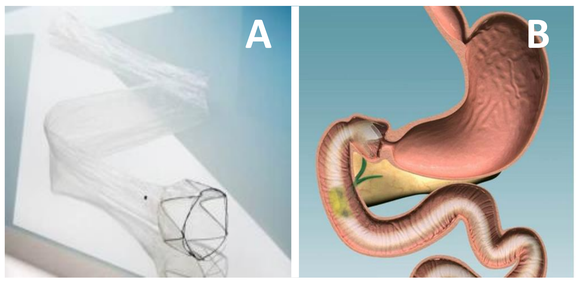


**Fig. 1A.** Photograph of EndoBarrier with crown anchor in foreground and tubing posteriorly; **1B** shows the device implanted in the proximal intestine with ingested food (yellow) passing within the device.

## 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 March 2024, data had been entered on 1101 EndoBarrier treated patients (from 36 centres in 11 countries), of whom 138 (16 centres in 8 countries: Australia, Brazil, Germany, Israel, Netherlands, Slovenia, Spain and United Kingdom) had both 9- and 12-month data entered.

| Parameter | n=238 |
|---|---|
| Age (years) | 49.2±13.4 |
| Sex (% male) | 47.5 |
| Ethnicity (% white) | 83 |
| BMI (kg/m$^2$) | 39.6±7.0 |

**Table 1:** Baseline demographics of the 238 patients with both 9- and 12-month data

### Fall in HbA1c

The fall in HbAc1 was affected by the fact that 16% of the 1101 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 little difference in weight loss or in the improvement in HbA1c, but would have led to a 31.9% 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 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) | 208 | 114.0±22.7 | 101.6±22.2 | 100.7±23.0 | -12.3±8.3 | -13.3±8.8 | <0.001 | <0.001 | 0.006 |
| All HbA1c (mmol/mol) | 177 | 72.1±22.4 | 56.1±14.7 | 55.5±16.6 | -16.0±19.0 | -16.6±19.9 | <0.001 | <0.001 | 0.262 |
| HbA1c ≥ 53 (mmol/mol) | 150 | 77.8±19.3 | 59.0±13.8 | 58.3±12.9 | -18.8±19.2 | -19.5±19.0 | <0.001 | <0.001 | 0.305 |
| HbA1c ≥ 64 (mmol/mol) | 117 | 83.1±18.7 | 60.7±14.7 | 59.9±13.7 | -22.3±20.0 | -23.1±19.7 | <0.001 | <0.001 | 0.335 |
| HbA1c ≥ 75 (mmol/mol) | 72 | 92.3±18.4 | 63.5±17.2 | 62.0±15.5 | -28.8±22.4 | -30.3±21.0 | <0.001 | <0.001 | 0.186 |
| HbA1c ≥ 86 (mmol/mol) | 44 | 101.1±18.6 | 67.8±18.1 | 65.6±15.6 | -33.3±25.5 | -35.5±22.9 | <0.001 | <0.001 | 0.134 |
| HbA1c ≥ 97 (mmol/mol) | 23 | 111.4±21.0 | 70.1±20.6 | 70.0±17.5 | -41.3±30.2 | -41.4±28.5 | <0.001 | <0.001 | 0.956 |

### Serious adverse events

**Table 3.** In the full registry, 47/1101 (4.3%) experienced serious adverse events (SAE). All patients with SAE made a full recovery, and most experienced benefits despite the SAE. 17/47 (31.9%) 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 | 26 | 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 DJBL | 1 | 1 | 0 |
| Early removal - gastric perforation – surgical removal as part of successful Roux-en-Y procedure | 1 | 1 | 0 |
| Total | 47 | 31 | 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..

## 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

Presented at EASD 60th Annual Meeting, Madrid, September 9-13, 2024