Duodenal-jejunal bypass liner for treatment of T2DM and obesity: 4-year outcomes in the first National Health Service (NHS) EndoBarrier service

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Abstract

Background and aims: EndoBarrier is a 60cm duodenal-jejunal bypass liner endoscopically implanted for up to one year and designed to mimic the bypass part of roux-en-Y bariatric surgery. There is uncertainty concerning the extent to which improvements associated with EndoBarrier treatment are sustained once the liner has been removed. We aimed therefore to establish an EndoBarrier service for refractory diabesity and to continue to monitor the people with diabetes after EndoBarrier removal.

Methods: Between October 2014 and November 2017, we implanted 62 EndoBarriers in our NHS service. All had been removed by November 2018. Outcomes were monitored in a registry.

Results: As of November 2021, all patients reached three years after EndoBarrier removal and of these 43/62 (69%) (mean \pm SD age 51.6 \pm 7.6 years, 55.8% male, 55.8% white ethnicity, median [IQR] diabetes duration 14.6 [8 - 21] years, 62.8% insulin-treated, mean±SD BMI 41.7±7.3 kg/m²) attended follow-up. In those who attended, during EndoBarrier implantation mean±SD HbA_{1c} fell by 20.6±19.6 mmol/mol from 76.3±19.2 to 55.7±11.1 mmol/mol (p<0.001) (by 1.9±1.8% from 9.1±1.8% to 7.2±1.0% [p<0.001]), weight fell by 17.4±9.1 kg from 123.3±30.0 kg to 105.9±30.8 kg (p<0.001), BMI fell from 41.7±7.3 to 35.6±7.7 kg/m² (p<0.001), systolic blood pressure from 138.7±14.4 to 125.4±14.7 mmHg (p<0.001), cholesterol from 4.6 ± 1.0 to 3.7 ± 0.7 mmol/L (p<0.001), and serum alanine aminotransferase from 30.8±17.2 to 19.3±11.2 U/L (p<0.001). In those taking insulin median (IQR) total daily insulin dose reduced from 114 (54-

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180) to 20 (0–65) units (n=27, p<0.001); 10/27 (37%) insulintreated people were able to discontinue insulin. Three years after EndoBarrier removal 33/43 (77%) maintained most of the improvement achieved with EndoBarrier whilst 10/43(23%) reverted to baseline. Of those deteriorating 9/10(90%) had depression and/or bereavement and/or major health problems/disability. 10/62(16%) required early EndoBarrier removal for adverse events or symptoms; all 10 fully recovered after removal and most derived significant benefit. Conclusions: Our data demonstrate that EndoBarrier is highly effective in people with refractory diabesity, with maintenance of significant improvement three years after removal in 77% of cases.

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Key words: EndoBarrier, duodenal–jejunal bypass liner, DJBL, obesity, type 2 diabetes, diabesity, bariatric surgery

Background

The numbers of people with type 2 diabetes (T2DM) and obesity are increasing relentlessly worldwide.¹ It is well established that optimised treatment can improve microvascular and macrovascular risk for people with diabetes.²⁻⁶ Nevertheless, in clinical practice many people with diabetes fail to achieve and maintain improvements in risk factors despite lifestyle advice and maximal doses of oral and injectable medications.⁷ Roux-en-Y gastric bypass (RYGB) is more effective than intensive anti-diabetes medical therapy and this has led to a joint statement by international diabetes organizations recommending more frequent metabolic surgery in treatment of T2DM.^{7,8}

RYGB is, however, a relatively invasive surgical treatment. As a less invasive alternative, the duodenal-jejunal bypass liner (DJBL) was developed to mimic the proposed small bowel mechanisms of RYGB.^{7,9} DJBL, also known as EndoBarrier, is a 60cm fluoropolymer liner that is implanted into the first part of the small intestine during an endoscopy procedure. It is anchored at the duodenal bulb, allowing nutrients to pass directly from the stomach into the jejunum.^{7,9,10} DJBL is left in place for up to one year, and then removed endoscopically. DJBL has been shown to reduce weight and improve glycaemic control in people with diabetes and obe-

82 THE BRITISH JOURNAL OF DIABETES

sity. ^{6,7,9,11-15} However, because it is not permanent, there is uncertainty over the extent to which improvements are maintained after removal of the device. ⁷ In view of the potential of this form of treatment to provide benefit to the many people with diabetes who remain with poor glycaemic control despite intensive anti-diabetes medical therapy, we established a National Health Service (NHS) EndoBarrier service in the UK to assess the effect of DJBL on weight and glycaemic control during the period of treatment and after device removal.

Since October 2014, we have implanted the device into 62 people with suboptimally controlled T2DM with obesity. We monitored outcomes in a registry. By November 2018 all devices were explanted and we were able to demonstrate considerable improvements in haemoglobin A_{1c} (HbA_{1c}), weight, systolic blood pressure, cholesterol, alanine aminotransferase as a marker of non-alcoholic fatty liver disease, 16 renal function, 17 and need for insulin. 6 Significant falls were demonstrated in the risk of coronary heart disease and stroke as indicated by the UKPDS Risk Engine v2.6 In the 10 out of 62 people with diabetes who required early removal due to side-effects all made a full recovery following device removal and most derived considerable benefit despite the early removal.⁶ One year after removal we were able to report that significant improvement was maintained in 78%.11 Ours was only the third, and the most detailed, study to report follow-up data 12 months after EndoBarrier removal, 7,11 and there are no studies with data beyond 12 months of follow-up. We recently strengthened our finding at one year after EndoBarrier removal by adding in people with diabetes treated with EndoBarrier in Birmingham in clinical trials. This led to a total of 90 EndoBarrier-treated people with diabetes and at one year after EndoBarrier 80% maintained significant improvement.18

Confidence in the longevity of EndoBarrier treatment would be increased further by improvement maintained beyond one year. We therefore aimed to follow our people with diabetes for a further two years to evaluate further the extent to which the benefits of EndoBarrier treatment were, or were not, sustained. We were recently able to demonstrate that by two years after EndoBarrier removal improvement was maintained in 73%. ¹⁹ We present here the results of assessment over a further year – at three years after removal of EndoBarrier.

Methods

We have described previously a comprehensive two-year pathway for the management of these people with diabetes who were seen at the Diabetes Centre at City Hospital in Birmingham, UK, in an NHS clinic specifically set up for the purpose. Patients were required to agree to take high-dose proton pump inhibitors (omeprazole 40 mg twice daily) and a daily multivitamin preparation throughout the period of EndoBarrier implantation. For the further two years of follow-up we continued to offer 3-6 monthly clinic consultations according to need with a Diabetes Specialist Nurse (DSN) and a diabetes physician, and with a dietician again according to need. Interim DSN consultations by phone or in clinic were also arranged sometimes according to need. We have also described the requirements of the insertion and removal procedures. The first EndoBar-

rier implantation in the NHS service was in October 2014 and the last one in November 2017. The last EndoBarrier was removed in November 2018. Thus, by November 2021 all patients had reached three years after EndoBarrier removal and the findings at that time are the subject of this report.

As previously described in detail,⁶ all patients had T2DM, were aged between 28 and 70 years, BMI >30 kg/m², and had tried diet, lifestyle and medications, including GLP-1 receptor agonists and, once available, SGLT2 inhibitors if within licence. Thus, the only options left for them were to start insulin, increase insulin further if already on insulin, or to have bariatric/metabolic surgery or alternative procedures not yet available on the NHS.6 HbA1c >58 mmol/ mol (7.5%) was generally required. Lower HbA_{1c} was acceptable only if patients were already established on insulin and it was considered that the patient's insulin treatment to maintain the lower HbA_{1c} was contributing significantly to the obesity.⁶ As previously detailed,6 we recorded baseline age, sex, ethnicity, smoking history, diabetes duration and medications. At baseline and at 3-month intervals during the period following EndoBarrier insertion and during the three years after removal, parameters measured included HbA_{1c}, weight, BMI, systolic blood pressure, alanine aminotransferase and diabetes medications including insulin dose if applicable. Side-effects were recorded, in particular gastrointestinal effects, and any serious adverse events leading to early removal of EndoBarrier, as has previously been reported.⁶ We also collected and have reported patient satisfaction as assessed with the NHS Friends and Family Test.⁶ Weight and height were measured on standard outpatient equipment. Biochemistry parameters were measured in the pathology department at City Hospital.

Statistical methods used were as follows. Baseline data were compared with follow-up data using the paired Student t-test for parametric data and the Wilcoxon signed-rank test for non-parametric data. Changes in insulin dose were assessed using the Chisquared test.

Results

Between October 2014, when the service commenced, and November 2017 when the last EndoBarrier was inserted, 62 people with diabetes received treatment with EndoBarrier. We have previously reported the outcomes during the year with EndoBarrier,6 during the year following removal, 11 and during the two years following removal in these people. 19 Three years after removal of the EndoBarrier, 43/62 (69%) attended for review and we report here the findings in those people.

The reasons for non-attendance in the 19/62 (31%) who did not attend are shown in table 1. Among those who did attend, at the time of EndoBarrier implantation, their mean \pm SD age was 51.6 \pm 7.6 years, 55.8% male, 55.8% white ethnicity, median (interquartile range) diabetes duration 14.6 (8-21) years, 62.8% insulintreated, mean \pm SD HbA_{1c} 76.3 \pm 19.2 mmol/mol (9.1 \pm 1.8%) and BMI 41.7 \pm 7.3 kg/m². They were thus people with longstanding poor glycaemic control and considerable obesity despite maximised available medications including GLP-1 receptor agonist therapy and SGLT2 inhibitor therapy once this became available.^{6,11}

As shown in table 2, during EndoBarrier treatment,

Table 1: The reasons for non-attendance in the 19/62 (31%) patients who did not attend follow-up

Reason for non attendance at follow up	n(%)
No reason given	7(36.8)
Too far to travel*	7(36.8)
Does not wish to take time off work to attend	2(10.6)
Severe depression	1(5.3)
Bariatric surgery**	1(5.3)
Patient died 9 months after removal of EndoBarrier***	1(5.3)

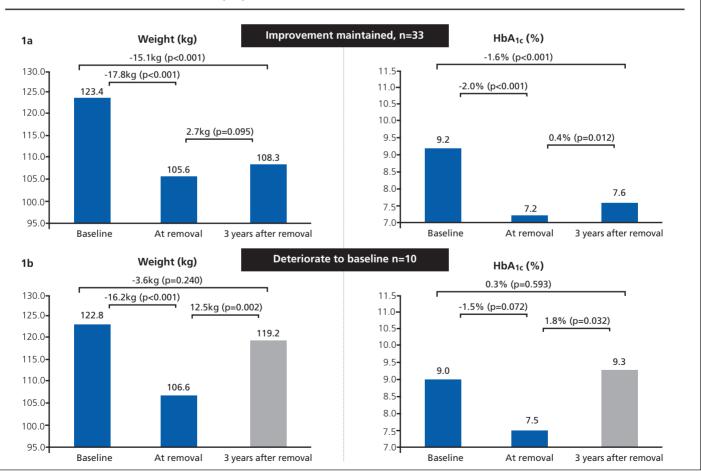
^{*}As we were the only NHS service providing EndoBarrier in the UK, we did get some referrals from very far away and it is perhaps understandable that these patients were not prepared to travel so far for follow up.

Table 2: Impact of EndoBarrier at the time of removal (EB explant) on weight, BMI, haemoglobin A_{1c} (HbA_{1c}), systolic blood pressure, cholesterol, alanine aminotransferase (ALT as a marker of non-alcoholic fatty liver disease and in the need for insulin in the 43 people with diabetes who attended for review 3-years after removal.

Parameter	Baseline	EB Explant	Difference	P-value
Weight (kg)	123.3±30.0	105.9±30.8	-17.4±9.1	<0.001
BMI (kg/m²)	41.7±7.3	35.6±7.7	-6.2±3.5	< 0.001
HbA _{1c} (%)	9.1±1.8	7.2±1.0	-1.9±1.8	< 0.001
HbA _{1c} (mmol/mol)	76.3±19.2	55.7±11.1	-20.6±19.6	<0.001
Systolic blood pressure (mmHg)	138.7±14.4	125.4±14.7	-13.3±16.2	<0.001
Cholesterol (mmol/L)	4.6±1.0	3.7±0.7	0.8±0.8	<0.001
ALT (U/l)	30.8±17.2	19.3±11.2	-11.5±18.3	< 0.001
Insulin daily dose* (n=30)	114 (54-180)	20 (0-65)	-94	<0.001

* Median(IQR). 10 of the 27 (37%) people with diabetes discontinued insulin

Figure 1. The weight and HbA_{1c} at baseline, at removal of EndoBarrier and 3-years after its removal in the 33/43 (77%) patients who maintained most of the improvement achieved in response to EndoBarrier **(1a)**, and the 10/43 (23%) who had deteriorated back to baseline by 3 years after its removal **(1b)**.



84 THE BRITISH JOURNAL OF DIABETES

^{**}She told us that her very positive experience with EndoBarrier led her to pay to have Roux-en-Y bariatric surgery privately and the surgery was very successful in her case.

^{***}In memoriam, it is noteworthy that during the year of EndoBarrier treatment her weight fell from 152.4 to 139.6 kg and that in the 6-months after removal, she lost more weight to 124.0 kg. HbA_{1c} fell from 122 to 50 mmol/mol during treatment and was 48 mmol/mol 6-months later. Her insulin requirement was 100 units daily prior to EndoBarrier but she required no insulin 6-months after EndoBarrier.

mean \pm SD HbA_{1c} fell by 20.6 \pm 19.6 mmol/mol from 76.3 \pm 19.2 to 55.7 \pm 11.1 mmol/mol (p<0.001) (by 1.9 \pm 1.8% from 9.1 \pm 1.8% to 7.2 \pm 1.0% [p<0.001]), weight fell by 17.4 \pm 9.1 kg from 123.3 \pm 30.0 kg to 105.9 \pm 30.8 kg (p<0.001), BMI fell from 41.7 \pm 7.3 to 35.6 \pm 7.7 kg/m² (p<0.001), systolic blood pressure from 138.7 \pm 14.4 to 125.4 \pm 14.7 mmHg (p<0.001), cholesterol from 4.6 \pm 1.0 to 3.7 \pm 0.7mmol/L (p<0.001), and serum alanine aminotransferase (a marker of liver fat)¹⁶ from 30.8 \pm 17.2 to 19.3 \pm 11.2 U/L (p<0.001). In those taking insulin, median (IQR) total daily insulin dose reduced from 114 (54–180) to 20 (0–65) units (n=27, p<0.001); 10/27 (37%) insulin-treated people with diabetes were able to discontinue insulin.

Three years after EndoBarrier removal, 33/43 (77%) maintained most of the improvement achieved with EndoBarrier whilst 10/43 (23%) reverted to baseline (Figure 1). Of those deteriorating, 9/10 (90%) had depression and/or bereavement and/or major health problems/disability. 10/62(16%) had early EndoBarrier removal for adverse events or symptoms; all 10 fully recovered after removal and most derived significant benefit.⁶ We have reported elsewhere the detail of these early removals,⁶ including the observation that several could have been avoided by patient compliance with advice given.⁶

Discussion

People with longstanding T2DM, with poor glycaemic control and obesity, especially those treated with insulin, find it difficult to lose weight and improve their glycaemic control. Many continue to have a high HbA_{1c} and to remain obese despite repeated diet and lifestyle advice and support and all available pharmaceutical therapies including GLP-1 receptor agonists and SGLT2 inhibitors. RYGB is an effective option in this situation,^{7,8} but is not without short- and longer-term complications.²⁰ Dumping syndrome is a common side effect after RYGB, occurring in about 85% of gastric bypass patients at some point after surgery.²⁰ We need new treatments that are less invasive than RYGB to help people with diabetes who remain obese and with poor glycaemic control despite lifestyle advice and maximal doses of oral and injectable medications. It is noteworthy that dumping syndrome was not reported by our EndoBarrier-treated people with diabetes.

We have shown here that following EndoBarrier treatment, amongst the 69% who attended follow-up three years later, 77% were able to maintain most of the improvement achieved during the year with EndoBarrier whilst 23% deteriorated back to baseline. It was noteworthy that most of those who reverted to baseline had experienced depression and/or bereavement and/or major health problems/disability during the three years following EndoBarrier treatment. These findings enhance our previous reports of considerable improvement in weight, glycaemic control, cardiovascular risk, renal function and a marker of liver fat as well as a reduction in the need for insulin that we found for EndoBarrier treatment in the first NHS service. 6,11,17-19 This is the first study to follow patients for three years after the removal of EndoBarrier.

The first United States Food and Drug Administration (FDA)



Key messages

- In people with refractory diabesity we previously demonstrated that EndoBarrier 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 now demonstrated that 3-years following removal of EndoBarrier, 77% of people with diabetes maintained most of the improvement achieved during EndoBarrier treatment, with 23% deteriorating to their baseline as they were prior to EndoBarrier. Those deteriorating tended to have depression and/or bereavement and/or major health problems/disability.
- Patient satisfaction levels were high and these results from the first NHS EndoBarrier service are encouraging for EndoBarrier as a treatment for people with long duration diabetes and obesity with poor glycaemic control despite other diabetes treatments

pivotal study of EndoBarrier was stopped early due to an hepatic abscess rate of 3.5%.7 A worldwide EndoBarrier registry has been established under the auspices of the Association of British Clinical Diabetologists (ABCD). There are currently data in the registry on 1,022 patients from 34 centres in 10 countries worldwide.²¹ The most recent analysis of data in the registry was presented at the 2022 European Association of the Study of Diabetes (EASD) meeting in Stockholm, 21,22 and the presentation is available for viewing online.²² It was pointed out in that presentation that the rate of hepatic abscess in the worldwide registry was 1.1% and that this contrasts with the 3.5% rate found in the USA pivotal study, suggesting that the pivotal study rate is an anomaly.²² In the new FDA pivotal study,²³ it is hoped that the hepatic abscess complication will be eliminated by the inclusion of daily temperature monitoring for early detection. Antibiotic cover at insertion and extraction of EndoBarrier is also being utilised to further mitigate risk.

Future use of EndoBarrier within the NHS is dependent on restoration of its CE mark, which was not renewed in November 2017,¹⁹ and it has been presumed that this was because of the hepatic abscess safety concern. The makers of EndoBarrier are now applying for restoration of the CE mark.¹⁹ Endoscopy units are widely available in healthcare systems, as are skilled endoscopists. People with refractory uncontrolled diabesity are also abundant worldwide and therefore should the safety concerns be successfully addressed, it would be relatively easy to make EndoBarrier widely available. The lessons we have learned with regard to measures to minimise serious adverse events would also be useful to future services.⁶

The improvements associated with EndoBarrier treatment, including improvements in glycaemic control, weight, blood

pressure and cholesterol are likely to reduce both the microvascular and macrovascular complications of diabetes as well as the general long-term health outlook for the people so treated.²⁻⁶ Our data demonstrate EndoBarrier to be highly effective in people with diabetes with refractory diabesity, with maintenance of significant improvement three years after removal in 77%. The benefits to the people with diabetes concerned are most readily appreciated from pictorial examples and from interviews with them, both of which can be viewed online.²⁴ With the reduction in insulin doses and with 37% of patients discontinuing insulin there is also considerable potential for cost savings associated with EndoBarrier. We have not undertaken a formal cost-benefit analysis but the potential cost-saving benefits are illustrated by the patient shown on pages 15-20 of our online pictorial examples.²⁴

Conflict of interest REJR has received speaker fees, and/or consultancy fees and/or educational sponsorships from BioQuest, GI Dynamics and Novo Nordisk. All other co-authors have nothing to declare.

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Author contributions REJR and PSG conceived the idea of this NHS service and set it up. REJR, PSG and MY were the diabetes specialists involved in delivering the service, ENF and MRA were the gastroenterologists who inserted and removed the EndoBarriers, RAA provided crucial assistance during these procedures and JPB provided anaesthesia. WB and SPI provided diabetes specialist nurse support to the patients and HG and TB dietetic support. MW administrated the project and MC was data administrator. REJR is the quarantor of this article.

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86 THE BRITISH JOURNAL OF DIABETES