The United Kingdom's first NHS EndoBarrier service for long-standing poorly controlled type 2 diabetes and obesity: outcomes one year after EndoBarrier removal

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Abstract

Aims: **EndoBarrier is a 60 cm duodenal–jejunal bypass liner endoscopically implanted for up to one year. It mimics the bypass part of Roux-en-Y bariatric surgery and reduces weight and HbA_{1c} while it is in situ. We aimed to assess the extent to which these improvements are sustained in people with diabetes in the year following removal.**

Methods**: Between October 2014 and November 2017 we implanted 62 EndoBarriers in an NHS service with all removed by November 2018. Outcomes were monitored in a registry.**

Results**: By November 2019, 46/62 (72%) (mean±SD age 51.5±7.7 years, 52% male, 54.3% white ethnicity, median (IQR) diabetes duration 14.5 (8–20) years, 67.4% insulin-treated and mean±SD body mass index (BMI) 41.6±7.1 kg/m^2) had attended and 16/62 (28%) did not attend their one-year post-EndoBarrier follow-up appointment. In those who attended, during EndoBarrier implantation mean±SD HbA_{1c} fell by 21.1±19.6 mmol/mol from 77.1±20.0 to 56.0±11.2 mmol/mol (p<0.001) (by 1.9±1.8% from 9.2±1.8% to 7.3±1.0% (p<0.001)), weight fell by 17.2±8.8 kg from 121.9±29.4 kg to 104.7±30.1 kg (p<0.001), BMI fell from 41.6±7.5 to 35.5±7.5 kg/m^2 (p<0.001), systolic blood pressure from 139.0±14.0 to 126.0±14.6 mmHg (p<0.001) and serum alanine aminotransferase from 30.0±16.9 to 18.8±11.0 U/L (p<0.001). Median (IQR) total daily insulin dose reduced from 104 (54–162) to 30 (0–62) units (n=31, p<0.001); 10/31 (32%) insulin-treated people with diabetes were able to discontinue insulin. One year post-EndoBarrier, 18/46 (39%) demonstrated fully sustained improvement, 18/46 (39%) partially sustained improvement and 10/46 (22%) reverted to baseline. Of those deteriorating, 9/10 (90%) had depression and/or bereavement; they also had less fall in weight and HbA_{1c} during EndoBarrier treatment. In the 16/62 (28%) who did not attend follow-up, reasons for non-attendance were too far to travel (25%), need to take time off work (6.3%), severe depression (6.3%) and death (6.3%). In 56.3% of cases no reason was given.**

Conclusion**: Our data demonstrate that EndoBarrier is highly effective in people with long-standing poorly controlled type 2 diabetes and obesity, with maintenance of significant improvement one year after removal in 78% of cases for whom data were available. As an endoscopic procedure it is relatively simple and non-invasive and it deserves further investigation.**

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

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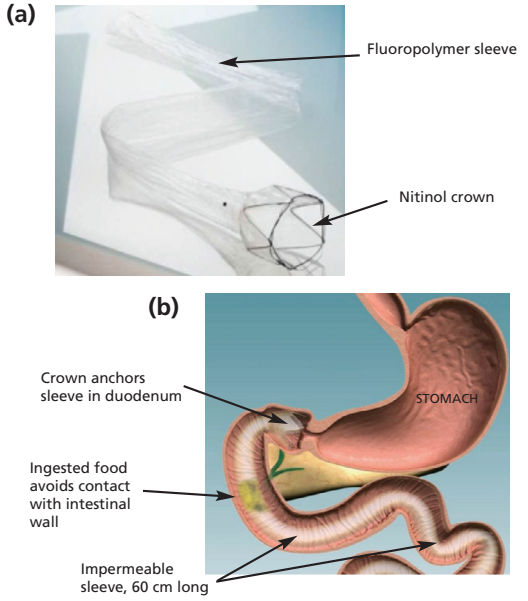
Introduction

Background and rationale

EndoBarrier® (GI Dynamics, Boston, USA), also known as the duodenal–jejunal bypass liner, 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 one 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 mimicking the bypass part of Roux-en-Y bariatric surgery.[1–3] The endoscopic insertion and removal of EndoBarrier are day case procedures, performed in less than an hour under general anaesthesia. This form of reversible bariatric procedure has been shown to reduce weight and improve glycaemic control in people with diabetes and obesity.[2–8]

As previously described in detail elsewhere,[8] we established in 2014 a National Health Service (NHS) service providing EndoBarrier treatment to people with long-standing poorly controlled type 2 diabetes and obesity which continued to be a problem despite all attempts to improve the situation with diet and lifestyle mea-

Figure 1. (a) The EndoBarrier device and (b) a diagram of the device in siut



Adapted from http://www.diabetologists-abcd.org.uk/Research/What_Endobarrier.htm.

sures as well as available diabetes medications. We treated 62 people with diabetes with EndoBarrier in this service.[8] By November 2018 all 62 had had the EndoBarrier removed and we were able to demonstrate[8] considerable improvements in haemoglobin A1c (HbA_{1c}), weight, systolic blood pressure, cholesterol, alanine aminotransferase as a marker of non-alcoholic fatty liver disease,[9] and in the need for insulin. There were also significant falls in the risk of coronary heart disease and stroke as indicated by the UKPDS Risk Engine v2.[8,10] We gave details of the 10 out of 62 people with diabetes requiring early removal due to side effects, all of whom made a full recovery following device removal with most deriving considerable benefit despite the early removal.[8]

Despite the dramatic impact of this endoscopic treatment on so many health parameters, there remains uncertainty regarding the extent to which such EndoBarrier-induced improvements are maintained following its removal.[2] We therefore aimed to follow our 62 people with diabetes during the year after EndoBarrier removal to assess the extent to which the benefits were sustained.

Methods

Study design and setting

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.[8] During the year following EndoBarrier removal there were telephone consultations between the patient and Diabetes Specialist Nurse (DSN) one week and one month after removal of EndoBarrier. Thereafter there were three-monthly clinic consultations with the DSN and diabetes physician, with dietician consultation according to need. Interim consultations with DSN by telephone or in clinic were also sometimes arranged according to need. We have also described the requirements of the insertion and removal procedures.[8] The first EndoBarrier implantation in the NHS service was in October 2014, with the last one in November 2017 and the last EndoBarrier was removed in November 2018. Thus, by November 2019, all had reached one year after EndoBarrier removal and the findings at that time are the subject of this report.

Participants

As previously described in detail,[8] all the patients had type 2 diabetes, were aged between 28 and 70 years, body mass index (BMI) >30 kg/m^2 and had tried diet, lifestyle and medications including glucagon-like peptide-1 (GLP-1) receptor agonists and, once available, sodium-glucose co-transporter-2 (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.[8] HbA_{1c} >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 their insulin treatment to maintain the lower HbA_{1c} was contributing significantly to the obesity.[8]

Variables

As previously detailed,[8] we recorded baseline age, sex, ethnicity, smoking history, diabetes duration and medications. At baseline and at three-month intervals during the period following EndoBarrier insertion and during the year 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, and any serious adverse events leading to early removal of EndoBarrier as has previously been reported.[8] We also collected and have reported patient satisfaction as assessed with the NHS Friends and Family Test.[8,11] Weight and height were measured on standard outpatient equipment. Biochemistry parameters were measured in the pathology department at City Hospital.

Sources of bias

Because we were auditing routine clinical practice, we could not interfere with standard care which might have impacted on the results – for example, medications for other conditions such as steroids for inflammatory conditions or medications for mental health. There was no control group for comparison and there was no blinding.

Study size

The study size was determined by following all the people we had treated by the time the Conformité Européenne (CE) Mark for EndoBarrier was suspended in November 2017.[12] This was 62, and we provide data here on all of these up until November 2019 – that is, one year after the last device removal which was in November 2018.

Statistical methods

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. When comparing data which was not paired (attended vs DNA), we used the unpaired Student t-test for parametric data and the Mann–Whitney U test for non-parametric data. Changes in insulin dose were assessed using the χ^2 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 and we have previously reported the outcomes during the year with EndoBarrier in all of these people.[8] One year after removal of the EndoBarrier, 46/62 (72%) people with diabetes attended follow-up and 16/62 (28%) did not attend. The reasons for their non-attendance are shown in Table 1. As word of our service spread, we had some referrals from far away. As a result, one of the important reasons for non-attendance was the distance required to travel to clinic for appointments. As previously detailed,[8] one of the patients had had their EndoBarrier removed after just 18 days for a gastrointestinal haemorrhage caused by non-compliance with mandatory dietary advice for the two weeks following EndoBarrier insertion. There were no follow-up data for this patient. We therefore had follow-up data after EndoBarrier insertion in 61/62 (98.4%) people with diabetes, 46 of whom attended and 15 of whom did not attend follow-up one year after EndoBarrier removal. Table 2 shows the baseline characteristics of the 46 people with diabetes who attended follow-up 12 months after removal (mean±SD age 51.5±7.7 years, 52% male, 54.3% white ethnicity, median (IQR) diabetes duration 14.5 (8–20) years, 67.4% insulin treated and mean±SD BMI 41.6±7.1 kg/m^2). The 15 people with diabetes who did not attend follow-up had a lower duration of diabetes, although this did not achieve statistical significance. The only significant difference was that the non-attenders were less likely to be taking insulin at baseline.

Table 3 compares the impact of EndoBarrier on weight and HbA_{1c} between the attenders and non-attenders. It can be seen that the non-attenders had significantly less weight loss in response to EndoBarrier than those who attended one year after removal (12.0±6.3 kg vs 17.2±8.8 kg, p=0.037).

Table 4 shows the main outcomes during the period of EndoBarrier implantation for the 46 people with diabetes who attended follow-up. Mean±SD HbA_{1c} fell by 21.1±19.6 mmol/mol from 77.1±20.0 to 56.0±11.2 mmol/mol (p<0.001) (by 1.9±1.8% from 9.2±1.8% to 7.3±1.0% (p<0.001)), weight fell by 17.2±8.8 kg from 121.9±29.4 kg to 104.7±30.1 kg (p<0.001), BMI fell from 41.6±7.5 to 35.5±7.5 kg/m^2 (p<0.001), systolic blood pressure from 139.0±14.0 to 126.0±14.6 mmHg (p<0.001) and serum alanine aminotransferase from 30.0±16.9 to 18.8±11.0 U/L (p<0.001). Median (IQR) total daily insulin dose reduced from 104 (54–162) to 30 (0–62) units (n=31, p<0.001); 10/31 (32%) insulin-treated people with diabetes were able to discontinue insulin.

Table 1 Reasons for non-attendance in the 16/62 (28%) people with diabetes who did not attend follow-up

Reason for non-attendance at follow-up	n (%)
No reason given	9 (56.3)
Too far to travel	4 (25.0)
Does not wish to take time off work to attend	1 (6.3)
Severe depression	1 (6.3)
Patient died 9 months after removal of EndoBarrier*	1 (6.3)

*Cause not EndoBarrier related. 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.

Table 2 Baseline characteristics of 46 people with diabetes who attended follow-up one year after EndoBarrier removal and 15 who did not attend follow-up

Parameter	Attended (n=46)	DNA (n=15)	P value
Age (years)	51.5±7.7	51.1±5.6	0.822
Sex (% male)	52	60	0.597
Ethnicity: % White % Asian-Indian % Afro-Caribbean	54.3 28.3 17.4	66.7 20 13.3	0.702
Weight (kg)	121.9±29.4	124.8±23.6	0.704
BMI (kg/m^2)	41.6±7.1	42.8±8.5	0.613
HbA_{1c} (mmol/mol)	77.1±20.0	89.7±27.6	0.119
HbA_{1c} (%)	9.2±1.8	10.4±2.5	0.119
Diabetes duration (median (IQR)) (years)	14.5 (8-20)	9.0 (6.0-12.0)	0.061
Taking insulin (%)	67.4	44.4	0.006

With regard to what happened to the people with diabetes during the year after removal of the EndoBarrier, Table 4 shows that all parameters of the group as a whole deteriorated although all except systolic blood pressure remained significantly lower than prior to EndoBarrier treatment. In particular, weight at 110.7±28.8 kg was 11.2±9.9 kg less than the baseline value of 121.9±29.4 kg (p<0.001) and HbA_{1c} at 67.8±19.6 mmol/mol (8.4±2.6%) was significantly less than the baseline value of 77.1±20.0 mmol/mol (9.2±1.8%) (p<0.001). Median (IQR) total daily insulin dose at 38 (0–80) units was considerably lower than baseline (104 (54–162) units) (p<0.001) and two further insulin-treated people with diabetes were able to discontinue insulin such that 12/31 (38.7%) insulin-treated subjects no longer required insulin.

The results shown in Table 4 for the group as a whole fail to expose the reality that many people with diabetes fully maintained the improvement achieved with EndoBarrier whilst others deteriorated back to their baseline state prior to EndoBarrier. To expose this reality we defined full maintenance of the improvement as no significant difference between the weight and HbA_{1c} at EndoBarrier removal and one year later. We defined partially maintained improvement as significant deterioration in both weight

Table 3 Impact of EndoBarrier treatment on mean±SD weight and HbA_{1c} in 46 people with diabetes who attended follow-up one year after EndoBarrier removal and 15 who did not attend follow-up

	Parameter	Baseline	Explant	Difference	P value 1	P value 2
Attended	Weight (kg)	121.9±29.4	104.7±30.1	-17.2±8.8	<0.001	0.037
DNA		124.8±23.5	112.8±24.6	-12.0±6.3	<0.001	
Attended	HbA_{1c} (mmol/mol)	77.1±20.0	56.0±11.2	-21.1±19.6	<0.001	0.095
DNA		89.7±27.6	57.9±12.5	-31.7±25.4	<0.001	
Attended	HbA_{1c} (%)	9.2±1.8	7.3±1.0	-1.9±1.8	<0.001	0.092
DNA		10.4±2.5	7.5±1.1	-2.9±2.3	<0.001	

P value 1 = baseline vs explant; P value 2 = difference attended vs difference DNA

Table 4 Impact of EndoBarrier treatment on mean±SD weight, BMI, HbA_{1c}, systolic blood pressure, alanine aminotransferase (ALT) and insulin daily dose in the 46 people with diabetes who attended follow-up one year after EndoBarrier removal showing values at baseline, at EndoBarrier explant and at one year after explant

Parameter	Baseline	Explant	Difference 1	P value 1	1 year after	Difference 2	P value 2
Weight (kg)	121.9±29.4	104.7±30.1	-17.2±8.8	<0.001	110.7±28.8	-11.2±9.9	<0.001
BMI (kg/m^2)	41.6±7.5	35.5±7.5	-6.1±3.3	<0.001	37.7±7.2	-3.9±3.4	<0.001
HbA_{1c} (mmol/mol)	77.1±20.0	56.0±11.2	-21.1±19.6	<0.001	67.8±19.6	-9.3±28.7	0.034
HbA_{1c} (%)	9.2±1.8	7.3±1.0	-1.9±1.8	<0.001	8.4±2.6	-0.8±2.6	0.034
Systolic BP (mmHg)	139.0±14.0	126.0±14.6	-12.9±16.0	<0.001	136.9±17.0	-2.1±19.1	0.463
ALT (U/l)	30.0±16.9	18.8±11.0	-11.1±17.8	0.001	21.2±10.2	-8.8±18.5	0.002
Insulin daily dose (median (IQR)) (n=31)*	104 (54-162)	30 (0-62)	-74	<0.001	38 (0-80)	-66	<0.001

Difference 1 = value at EndoBarrier explant minus value at baseline; Difference 2 = value at 1 year after EndoBarrier explant minus value at baseline; P value 1 = value at EndoBarrier explant versus value at baseline; P value 2 = value at 1 year after EndoBarrier explant versus value at baseline
*12/31 (38.7%) insulin treated patients were able to discontinue insulin.

and HbA_{1c} from between EndoBarrier removal and one year after removal but continued significant improvement in both weight and HbA_{1c} compared with baseline. Finally, we defined deterioration to baseline as no significant difference between baseline and one year after EndoBarrier removal. Using these definitions, as illustrated in Figure 2, 18/46 (39%) demonstrated fully sustained improvement in weight and HbA_{1c}, 18/46 (39%) partially sustained improvement, with 10/46 (22%) reverting to baseline. Figures 3a–c show the weight and HbA_{1c} for those who fully sustained the improvement, partially sustained the improvement and deteriorated to baseline, respectively. It was noteworthy that those who deteriorated to baseline reported to us many problems in their lives and 9/10 (90%) had depression or bereavement. Table 5, however, shows that the people with diabetes who went on to deteriorate back to baseline had had less fall in weight and HbA_{1c} during the period of EndoBarrier treatment than those who maintained or partially maintained the improvement.

As changes in medication during the year following EndoBarrier removal could confound the results, Table 6 shows the medications at the time of EndoBarrier removal and one year after removal in the three groups. It can be seen that there were no changes of note. Table 7 shows the number of people with diabetes taking insulin and the average number of daily units of insulin per patient in each group at baseline, at the time of

Figure 2. Figure 2 One year after removal of EndoBarrier, 18/46 (39%) fully sustained the improvement achieved during EndoBarrier treatment, 18/46 (39%) partially sustained this improvement and 10/46 (22%) who deteriorated back to their baseline as they were prior to EndoBarrier

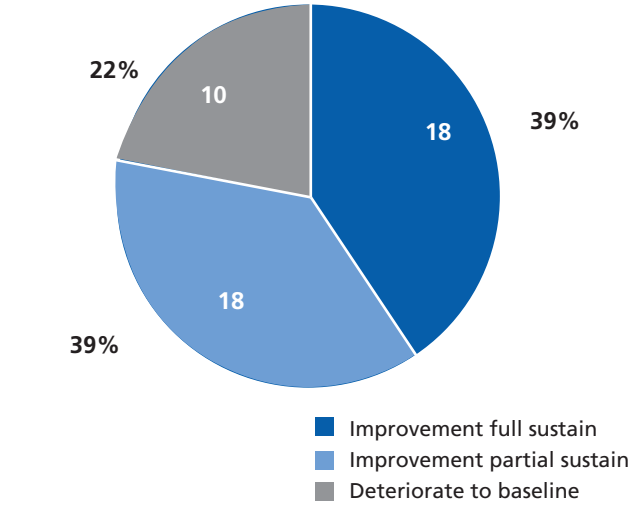


Figure 3. Weight and HbA_{1c} at baseline, at explant and one year after explant in (a) the 18/46 (39%) who fully maintained the improvement achieved during EndoBarrier treatment, (b) the 18/46 (39%) who partially maintained this improvement and also (c) the 10/46 (22%) who deteriorated back to their baseline as they were prior to EndoBarrier.

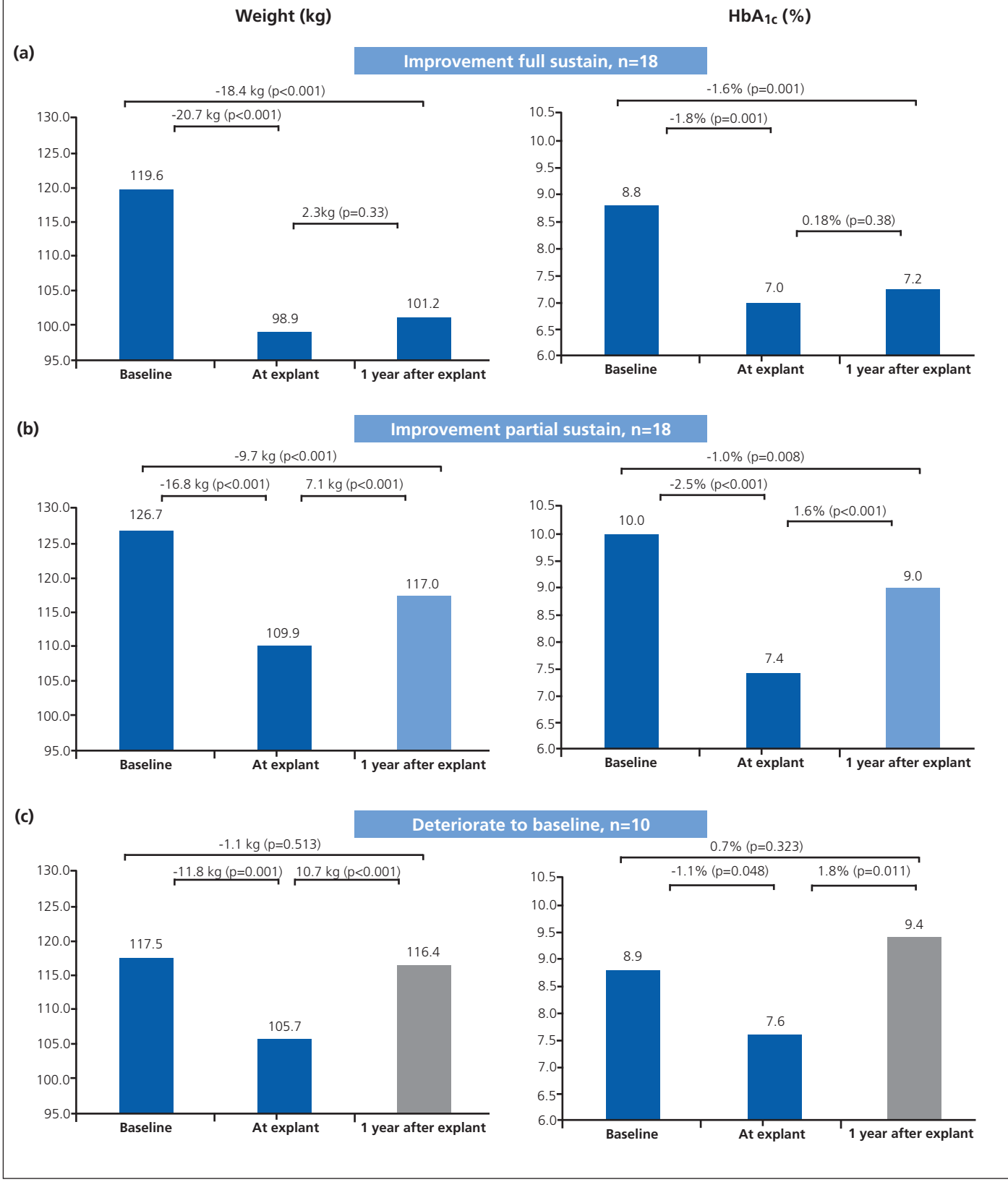


Table 5 People with diabetes who went on to deteriorate back to baseline had had less fall in mean weight and HbA_{1c} during the period of EndoBarrier treatment than those who maintained or partially maintained the improvement

	Weight loss during EndoBarrier treatment	Fall in HbA_{1c} during EndoBarrier treatment
Fully sustained (n=18)	20.7 kg	1.8%
Partially sustained (n=18)	16.8 kg	2.5%
Deteriorated to baseline (n=10)	11.8 kg	1.1%

EndoBarrier removal and one year after EndoBarrier removal. It can be seen that the amount of insulin required by people with diabetes in all three groups reduced during the year of EndoBarrier treatment but that, in the group who sustained the improvement, the insulin requirement continued to fall after EndoBarrier removal whereas in the partially sustained group it rose although remaining at only 53.5% of baseline. In the group who deteriorated the insulin requirement rose most to 85.7% of baseline.

Discussion

People with long-standing type 2 diabetes, 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 GLP-1 receptor agonists and SGLT2 inhibitors. We need new treatments to help such people.

Key results

We have shown here that in the year following EndoBarrier treatment, amongst the 72% who attended follow-up a year later, 39% were able to sustain the full improvement achieved during the year with EndoBarrier (ie, they showed no significant difference between weight and HbA_{1c} at EndoBarrier removal and one year later), 39% partially sustained the improvement (ie, they showed a significant deterioration in both weight and HbA_{1c} between EndoBarrier removal and one year after removal but remained significantly improved in both weight and HbA_{1c} compared with baseline) and 22% deteriorated to baseline (ie, they showed no significant difference between baseline and one year after EndoBarrier removal). It was noteworthy that those who reverted to baseline experienced less improvement in weight and HbA_{1c} during the year with EndoBarrier and most had experienced depression or bereavement during the year following EndoBarrier. These findings enhance our previous report of considerable improvement in weight, glycaemic control, a marker of liver fat and cardiovascular risk, as well as reduction in the need

Table 6 Medications at the time of EndoBarrier removal and one year after EndoBarrier removal in the 18/46 (39%) people with diabetes who fully sustained the improvement, 18/46 (39%) who partially sustained the improvement and the 10/46 (22%) who deteriorated back to baseline

Medication	Sustained improvement		Partially sustained improvement		Deteriorated to baseline	
	At explant	1 year later	At explant	1 year later	At explant	1 year later
Metformin	15/18 (83.3%)	14/18 (77.8%)	17/18 (94.4%)	16/18 (88.9%)	9/10 (90%)	9/10 (90%)
GLP-1 receptor agonist	15/18 (83.3%)	14/18 (77.8%)	11/18 (61.1%)	14/18 (77.8%)	7/10 (70%)	7/10 (70%)
SGLT2 inhibitor	6/18 (33.3%)	8/18 (44.4%)	8/18 (44.4%)	8/18 (44.4%)	3/10 (30%)	4/10 (40%)
Pioglitazone	3/18 (16.7%)	6/18 (33.3%)	5/18 (27.8%)	6/18 (33.3%)	3/10 (30%)	3/10 (30%)
Sulfonylurea	1/18 (5.6%)	0/18 (0%)	1/18 (5.6%)	0/18 (0%)	0/10 (0%)	0/10 (0%)
DPP4 inhibitor	1/18 (5.6%)	1/18 (5.6%)	2/18 (11.1%)	2/18 (11.1%)	2/10 (20%)	1/10 (10%)
Metiglinide	1/18 (5.6%)	0/18 (0%)	1/18 (5.6%)	1/18 (5.6%)	1/10 (10%)	1/10 (10%)
Insulin	5/18 (27.8%)	4/18 (22.2%)	9/18 (50%)	10/18 (55.6%)	5/10 (50%)	5/10 (50%)

Table 7 Number of people with diabetes taking insulin and average number of daily units of insulin per person in the group at baseline, at the time of EndoBarrier removal and one year after EndoBarrier removal in the 18/46 (39%) who fully sustained the improvement, 18/46 (39%) who partially sustained the improvement and also the 10/46 (22%) who deteriorated back to baseline

Outcome 1 year after EndoBarrier removal	Baseline		At explant		1 year later	
	Number (%) taking insulin	Average units of insulin	Number (%) taking insulin	Average units of insulin	Number (%) taking insulin	Average units of insulin
Sustained improvement	13/18 (72.2%)	77	5/18 (27.8%)	23	5/18 (27.8%)	9
Partially sustained improvement	11/18 (61.1%)	112	9/18 (50%)	38	10/18 (55.6%)	60
Deteriorated to baseline	6/10 (60%)	50	5/10 (50%)	33	5/10 (50%)	43

for insulin that we found for EndoBarrier treatment in the first NHS service.[8]

Strengths

People with diabetes on insulin and with elevated BMI are a difficult to treat group. People in this observational cohort study had a median diabetes duration of 14.5 years and 67.4% were insulin treated. We need to add to our existing armamentarium of interventions. In the current climate it would be difficult to offer bariatric surgery to most of this cohort of people both in terms of logistics and funding. Our study demonstrated considerable clinical benefit to such a group of people and also demonstrated that, with sufficient clinical support during follow-up, this benefit can be maintained in most.

Limitations

As reported in our original paper,[8] the main limitation of this audit of a service is the lack of a control group. All the people involved had a long history of attempts at weight loss and using diabetes medications known to help with weight loss, such as GLP-1 receptor agonists and SGLT2 inhibitors, but nevertheless we cannot be sure in this cohort study what contribution there might have been from a placebo effect or the more intense follow-up. Also, we have only limited information about the 28% of people who did not attend follow-up. We know that many felt it was too far to travel to clinic (Table 1). They were also less likely to be taking insulin at baseline (Table 2) and they lost less weight during the treatment with EndoBarrier (Table 3), but we do not know the extent to which they maintained or did not maintain the improvements.

Serious adverse events

In our previous publication[8] we gave details of the 10 out of 62 people with diabetes requiring early removal due to side effects (four gastrointestinal haemorrhage, two liver abscess, one other abscess, and three gastrointestinal symptoms), all of whom made a full recovery following device removal with most deriving considerable benefit despite the early removal.[8] We also stated that a number of these adverse events could have been avoided by patient compliance with mandatory advice and pointed out that, in future services, such problems could be reduced by stronger re-enforcement of such advice. In particular: (1) to strictly follow a liquid diet in the first week after implantation of EndoBarrier and a pureed diet during the second week; (2) to ensure that all food is thoroughly chewed before swallowing, in particular food such as steak; and (3) to comply with mandated anti-acid medications (proton pump inhibitors or H_2-receptor antagonists).

In the current pivotal trial with EndoBarrier in the USA,[13] daily temperature monitoring is being mandated with remote monitoring such that the liver abscess complication can be detected and treated early. Such a precaution could further reduce complications and should be considered in the set-up of future services.

Interpretation

We have previously pointed out that the improvements associated with EndoBarrier treatment are likely to impact both microvascular and macrovascular complications and the general long-term health outlook for the people so treated.[8] We have shown here that, in the year following EndoBarrier removal, 78% of people with diabetes for whom data were available were able to maintain significant improvement, which is encouraging for EndoBarrier as a potential relatively simple treatment sitting between diet and lifestyle measures with pharmacological therapies on the one hand and bariatric surgery on the other.

A meta-analysis of EndoBarrier treatment in people with type 2 diabetes and obesity[2] identified two studies with follow-up data 12 months after EndoBarrier removal[14,15] and concluded that, whilst the weight remained significantly lower than baseline (10.7 kg), the HbA_{1c} was not significantly different compared with baseline.[2] In one of these studies[14] the BMI, HbA_{1c} and duration of diabetes was notably less than in our study. In the other study,[15] whilst the baseline HbA_{1c} and duration of diabetes were similar to our study, the baseline BMI was again considerably less. Neither study considered the possibility that within the overall result there might have been groups who maintained the improvement and deteriorated to baseline, as we have done. However, one of the studies[15] compared people with diabetes with HbA_{1c} ≤7% at EndoBarrier explant with those with HbA_{1c} >7% and demon-

Key messages

- In people with obesity, poor glycaemic control and long duration of diabetes, we have previously demonstrated that EndoBarrier led to a considerable improvement in weight and microvascular risk, as indicated by improvement in blood pressure and glycaemic control. We also demonstrated a significant reduction in cardiovascular risk as assessed by the UKPDS risk engine.
- We have now demonstrated that a year following removal of EndoBarrier, 39% of people with diabetes maintained the full improvement achieved during EndoBarrier treatment, 39% partially maintained this improvement, with 22% deteriorating to their baseline as they were prior to EndoBarrier. Those deteriorating tended to have depression or bereavement.
- We previously demonstrated that all people with diabetes requiring early removal for serious adverse events or side effects (16%) fully recovered, and despite early removal, most derived benefit. In many, such problems could have been avoided by improved education and vigilance.
- 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.

strated that the former maintained the improvement one year after EndoBarrier, suggesting that their people with diabetes, like ours, divided into groups who responded differently. The apparently greater success in our study may also be related to the level of support we gave to our people with diabetes during the year after EndoBarrier, as described in the Methods section.

EndoBarrier treatment requires only a relatively quick and easy endoscopy procedure and it is noteworthy that endoscopy units and skilled endoscopists are ubiquitous throughout the NHS. In the context of the diabesity pandemic,[16] there is a need for simpler treatments that are less invasive than bariatric surgery for the many people with obesity and poorly controlled diabetes despite diet and lifestyle and pharmaceutical interventions. As demonstrated by their responses to the NHS Friends and Family Test,[8,11] EndoBarrier was popular among those who received the treatment, and the benefits to those concerned are most readily appreciated from the pictorial examples[17] and from interviews with them,[18] both of which can be readily viewed online.[17,18] EndoBarrier therefore deserves further investigation as a potential treatment for wider use in people with long-standing poorly controlled type 2 diabetes and obesity, especially bearing in mind the cardiovascular and microvascular risks to these people if they are not given additional treatment.

Generalisability

Future use of EndoBarrier within the NHS is dependent on restoration of the CE mark, which was not renewed in November 2017 by the notified body at the time for reasons that are not entirely clear.[12] In 2021 the makers of EndoBarrier are re-applying for restoration of the CE mark and are hopeful that it will be achieved.[19] In the light of our experience with EndoBarrier and the obvious benefits to the people we have treated, we also hope for the restoration of permission to use this form of treatment in the UK. With the increased safety measures that we would recommend, as detailed above, we believe the risk benefit ratio is strongly towards benefit. Endoscopy units are ubiquitous throughout the NHS, as are skilled endoscopists. There is a worldwide pandemic of type 2 diabetes and obesity,[16] and thus there are also very many people with long-standing poorly controlled type 2 diabetes and obesity throughout the NHS. Therefore, should permission for use in the UK be restored, it would be relatively easy to make EndoBarrier treatment widely available.

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