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Improvement in Renal Function in Participants in the First UK National Health Service (NHS) EndoBarrier Service for Uncontrolled Diabesity

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Abstract

Aims: EndoBarrier, a 60cm proximal intestinal liner, endoscopically implanted for up to one-year, reduces weight and HbA1c. As the risk of progressive chronic kidney disease (CKD) is increased by high BMI, we assessed the impact of EndoBarrier on renal function.

Methods: Between October 2014 and November 2017 we implanted EndoBarriers in 62 patients with sub-optimally controlled diabesity in our NHS service; by November 2018 all were explanted. Clinical and laboratory outcomes, including routinely performed kidney function testing by serum creatinine and MDRD eGFR, were collected in a registry

Results: In 61 patients (aged 51.4±7.2 years, 54.1% male, 57.4% europid, diabetes duration 12.0 (8.0-19.5) years, 57.4% insulin-treated, BMI 41.9±7.4 kg/m2) with implant and explant data, weight fell by 15.9±8.5 kg from 122.6±27.9 to 106.7±28.9 kg (p<0.001), BMI from 41.9±7.4 to 36.2±7.6 kg/m2 (p<0.001) and systolic blood pressure (BP) from 138.5±15.0 to 125.8±14.6 mmHg (p<0.001), mean±SD. HbA1c fell by 23.7±21.4 mmol/mol from 80.2±22.5 to 56.5±11.5 mmol/mol(p<0.001), cholesterol from 4.7±1.4 to 3.9±0.9 mmol/L (p<0.001) and alanine-aminotransferase (ALT – a marker of liver fat) from 33.2±19.8 to 19.5±11.4 U/L (p<0.001). In the 35 insulin-treated patients median (IQR) insulin dose reduced from 100 (54-140) to 40 (0-70) units (p<0.001) with 10/35 (28.6%) discontinuing insulin. With regard to renal function, mean±SD serum creatinine improved by 5.5±15.4 µmol/L from 91.7±47.7 to 86.2±45.7 µmol/L (p=0.007) and estimated-Glomerular-Filtration-Rate (abbreviated MDRD equation) improved by 5.8±10.7 ml/min/1.73m2 from 84.3±25.2 to 90.1±26.4 ml/min/1.73m2 (p<0.001). Five patients had raised serum creatinine (>133 µmol/L) prior to Endobarrier; after implantation in four of these creatinine reduced and in two normalised. The four patients with renal impairment who sustained improvement had large weight loss (19.3-34.4 kg), the patient without improvement had only 6.6 kg weight loss.

Conclusion: As well as previously documented improvements in weight, HbA1c, BP, ALT and cholesterol, EndoBarrier was associated with improvements in renal function. These observational findings warrant further investigation through prospective study of the impact of such bariatric interventions on progressive CKD.

Keywords: EndoBarrier; Weight loss; Cholesterol; Endoscopic insertion; Blood pressure; Glycaemic control

Abbreviations: CKD: Chronic Kidney Disease; BP: Blood Pressure; ALT: Alanine-Aminotransferase; eGFR: Estimated Glomerular Filtration Rate

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 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. This form of reversible bariatric procedure has been shown to reduce weight and improve glycaemic control in patients with diabetes and obesity [2-7].

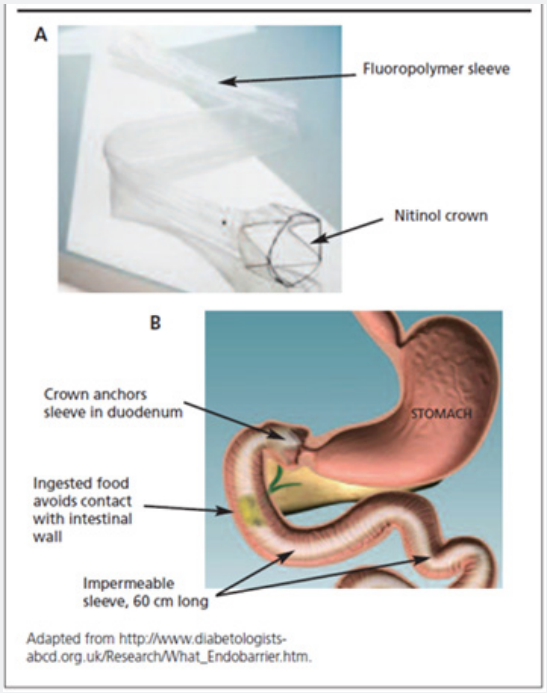

Figure 1A): The endobarrier device and (B) A diagram of the device in situ.

We have previously reported our experience from setting up the first NHS EndoBarrier service for advanced diabesity and we reported the outcomes for all 62 of the patients we treated with EndoBarrier [7]. We demonstrated that in people with obesity and poor glycaemic control and a long duration of diabetes, EndoBarrier led to a considerable improvement in weight, and microvascular risk as indicated by improvement in blood pressure and glycaemic control [7]. There was also a reduction in cardiovascular risk as assessed by the UK PDS risk engine [7]. There was a reduction in a marker of fatty liver and in those on insulin a substantial reduction in required insulin dose, including 30% discontinuing insulin [7].

As the risk of progressive chronic kidney disease is increased in individuals with high BMI [8], we assessed the impact of EndoBarrier induced weight loss on renal function in this same group of patients.

Objectives: Specifically, we aimed to assess serum creatinine and estimated glomerular filtration rate (eGFR) before EndoBarrier implantation and at explant. We aimed to assess these parameters alongside the other parameters collected at these time points, in particular weight, HbA1c and systolic blood pressure.

Methods

Study Design and Setting: We designed a comprehensive two-year pathway, as previously described [7]. Patients were seen at the Diabetes Centre at City Hospital in Birmingham, UK, in NHS clinics specifically set up for the purpose. The Gastroenterologists responsible for EndoBarrier implantation and explantation saw the patients in a different clinic in the same setting. As previously described [7], the implantation and explantation procedures were carried out, with the support of an anaesthetist, in an endoscopy theatre suite equipped with Fluoroscopy screening. The first EndoBarrier implantation was in October 2014 and the last one in November 2017 with the last EndoBarrier explanted in November 2018 [7].

Participants: The patients had type 2 diabetes, were aged between 28 and 70 years, BMI >30 kg/m^2, and must have already tried diet, lifestyle and other medications, including GLP-1 receptor agonists and SGLT2 inhibitors, once these became available [7]. Thus, the only options left were; to start insulin, to increase insulin further if already on insulin, or bariatric surgery/procedure [7]. HbA1c >58 mmols/mol (7.5%) at time of assessment was required unless the patient's insulin treatment to maintain a HbA1c lower than this threshold was contributing significantly to the obesity [7]. Patients with a HbA1c > 58 mmols/mol (7.5%) at assessment, who had a HbA1c below this threshold immediately before the planned Endobarrier implantation, proceeded to implantation [7]. Patients taking aspirin or other antiplatelet medication that could not safely be stopped were excluded [7]. Patients were tested (stool sample) for *Helicobacter pylori* (*H. pylori*) and those who were test positive were excluded unless this was eradicated by antibiotic treatment [7].

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Variables: We recorded baseline age, sex, ethnicity, smoking history, diabetes duration and medications. We measured at baseline and at 3 monthly intervals following EndoBarrier implantation, HbA1c, weight and BMI, serum creatinine, eGFR, systolic blood pressure, cholesterol, HDL cholesterol, cardiovascular risk as assessed by the UKPDS risk engine v2 [9], alanine aminotransferase (a marker of fatty liver disease [7]), diabetes medications – in particular insulin dose if applicable [7]. Side effects were recorded, in particular gastro-intestinal side effects and any serious adverse events leading to early removal of the EndoBarrier [7]. Patient satisfaction was assessed using the NHS friends and family test [10]. Weight and height were measured on standard out-patient equipment. Biochemistry parameters were measured in the pathology department at City Hospital.

Sources of bias: As we were auditing routine practice, we could not interfere with standard care which might have impacted on the results, for example medications for hypertension that may have been added in during the year of treatment that may have had an impact and medications for other conditions such as steroids for inflammatory conditions or medications for mental health.

Study size: This was an overservational study to report early outcomes in all patients we treated with EndoBarrier [7]. After implantation into 62 such patients, the CE mark for EndoBarrier was suspended (November 2017 [11]) and we present here the data on all 62 patients up until explantation of the last one in November 2018.

Statistical methods: The impact of EndoBarrier on the parameters measured at follow-up was assessed by comparing the parameter in the last value measured prior to explantation with the baseline value using a paired student t-test. As all patients had to attend in order to have EndoBarrier explantation, explantation data was obtained on all patients except for one whose explantation occurred within 3 weeks due to non-compliance with the safety advice [7].

Results

In our previous publication [7], we documented the 174 patients referred to our service between October 2014 and November 2017 of whom 62 (36%) proceeded to EndoBarrier and 112 (64%) did not receive EndoBarrier treatment. Of the 62 patients accepted for EndoBarrier one failed to comply with the mandatory dietary advice to only eat pureed food during the second week after EndoBarrier insertion; this led to gastro-intestinal haemorrhage so that he required EndoBarrier removal [7]. Table 1 shows the baseline characteristics of the remaining 61 patients (aged 51.4±7.2 years, 54.1% male, 57.4% europid, diabetes duration 12.0 (8.0-19.5) years, 57.4 % insulin-treated, BMI 41.9±7.4 kg/m^2) with implant and explant data.

Table 1: Baseline characteristics of 61 patients with implant and explant data.

Parameter	N=61
Age (years)	51.4±7.2
Sex (% Male)	54.1
Ethnicity (% Europid)	57.4
BMI (kg/m^2)	41.9±7.4
HbA1c (mmol/mol) HbA1c (%)	80.2±22.5 9.5±2.1
Diabetes duration (years)	12.0(8-19.5)
Taking insulin (%)	57.4

Table 2 shows the main outcomes during the period of EndoBarrier treatment as has been reported previously [7]. In particular we point out the mean±SD HbA1c fell by 23.7±21.4mmol/mol from 80.2±22.5 to 56.5±11.5mmol/mol (p<0.001), weight fell by 15.9±8.5kg from 122.6±27.9 to 106.7±28.9kg (p<0.001), BMI fell from 41.9±7.4 to 36.2±7.6 kg kg/m^2 (p<0.001) and systolic blood pressure fell from 138.5±15.0 to 125.8±14.6 mmHg (p<0.001).

Table 2: The impact of EndoBarrier treatment on mean±SD weight, HbA1c and CVD risk factors and alanine-aminotransferase (ALT – a liver fat marker) in 61 patients. There were highly significant falls in all parameters involved in CVD risk assessment other than HDL cholesterol which remained unchanged.

Parameter	Baseline	Atexplant	Difference	P-value
Weight (kg)	122.6±27.9	106.7±28.9	-15.9±8.5	<0.001
BMI (kg/m^2)	41.9±7.4	36.2±7.6	-5.7±3.2	<0.001
HbAIc (mmol/mol)	80.2±22.5	56.5±11.5	23.7±21.4	<0.001
HbA1c (%)	9.5±2.1	7.3±1.1	2.2±2.0	<0.001
Systolic blood pressure (mmHg)	138.5±15.0	125.8±14.6	12.7±16.2	<0.001
Cholesterol (mmol/L)	4.71±1.35	3.86±0.86	0.86±1.13	<0.001
HDL (mmol/L)	1.13±0.27	1.10±0.30	0.04±0.22	0.135
ALT (U/I)	33.2±19.8	19.5±11.4	-13.7±20.1	<0.001
Insulin daily dose (Median (IQR) (n=35)*	100(60-135)	40(0-70)	-60	<0.001

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Table 3 shows the impact of EndoBarrier treatment on renal function as measured by serum creatinine and eGFR. Serum creatinine fell by a mean of 5.5 ± 15.4 µmol/L from 91.7 ± 47.7 to 86.2 ± 45.7 µmol/L (P = 0.007). eGFR increased by 5.8 ± 10.7 ml/min/1.73 m^2 from 84.3 ± 25.2 to 90.1 ± 26.4 ml/min per 1.73 m^2 (P < 0.001).

Five patients had a raised serum creatinine (> 133 µmol/L) prior to EndoBarrier treatment. During EndoBarrier treatment in 4 of these patients the creatinine reduced, and in 2 the creatinine normalised. Table 4 shows the before and after creatinine data for these 5 patients with the weight data given alongside. It is noteworthy that the 4 patients with renal impairment who sustained an improvement in kidney function had a large weight loss (19.3 – 33.4 kg) whereas in the patient without improvement in renal function the weight loss was only 6.6 kg.

Table 3: EndoBarrier had a significant impact on renal function.

Parameter	Baseline	At Explant	Difference	P-value
Serum Ceratinine (umol/L)	91.7±47.7	86.2±45.7	5.5±15.4	0.007
eGFR (ml/min/1.73m^2)	84.3±25.2	90.1±26.4	5.8±10.7	<0.001

Table 4: Five patients had a raised serum creatinine (>133µmol/L) prior to EndoBarrier; after implantation in four of these patients the creatinine reduced and in two creatinine normalized.

Patient	Creatinine at Baseline (umol/L)	Creatinine at Explant (umol/L)	Weight at Baseline (Kg)	Weight at Explant (Kg)	Weight Loss (Kg)	Comment
Patient 1	348	281	128.2	108.9	19.3	Big weight loss creatinine improved
Patient 2	284	329	131.2	124.6	6.6	Small weight loss creatinine deteriorated
Patient 3	166	152	122.4	98.8	23.6	Big weight loss creatinine improved
Patient 4	153	106	92.4	73	19.4	Big weight loss creatinine normalized
Patient 5	153	133	145.4	111	34.4	Big weight loss creatinine normalized

Early removal: As previously documented 10 of the 62 patients implanted with EndoBarrier (16%) required early removal, 4 for gastro-intestinal haemorrhage, 2 for liver abscess, 1 for another abdominal abscess and 3 for gastro-intestinal symptoms [7]. In several cases there were issues with compliance which led to early removal and we have previously reported the detail of this [7]. All made a full recovery following device removal and most derived benefit despite the early removal [7].

Patient satisfaction: As previously reported [7], patients reported considerable increase in fitness and wellbeing and in the NHS friends and family test (10) in response to the question "how likely would you be to recommend this treatment to friends and family?", 84% replied "extremely likely" with a further 12% reporting "likely".

Discussion

Key results: As previously documented, EndoBarrier resulted in substantial weight loss (mean 15.9 kg), improvement in glycaemic control (mean 23.7 mmols/L from 82.2 – 56.5 mmols/L), significant reduction in a marker of fatty liver, and improvement in cardiovascular risk factors, and for those on insulin a substantial reduction in insulin dose with 28.6% insulin-treated patients discontinuing insulin [7]. Patients reported considerable increase in fitness and wellbeing and all patients with early removal because of serious adverse events made a full recovery and most derived significant benefit despite the early removal [7]. Alongside these previously documented improvements EndoBarrier was also associated with improvement in renal function (mean serum creatinine fall by 5.5 µmol/L from 91.7 µmol/L to 86.2 µmol/L and mean eGFR increasing by 5.8 ml/min per 1.73 m^2 from 84.3 to 90.1 ml/min per 1.73 m^2).

Limitations: The main limitation of this study is lack of a control group. The patients had previously tried to lose weight of many years and all had tried medications known to help with weight loss, such as GLP-1 receptor agonists and SGLT2 inhibitors once they became available. Nevertheless, we cannot be sure from this cohort study what contribution there might have been from the placebo effect. In the current pivotal study with EndoBarrier of the United States Food and Drug Administration (FDA) [12], there is a sham control group who will receive an endoscopic examination without insertion of an EndoBarrier in a double-blind randomised fashion to address this issue. Nevertheless, it seems unlikely that a placebo affect would achieve anything like the degree of improvement in weight and metabolic outcomes achieved in the current cohort study. Regarding renal function testing, measured GFR may have given a more accurate assessment of the impact of Endobarrier on kidney function. However, the MDRD eGFR has good accuracy for estimation of kidney function

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and mGFR is not deliverable in a routine service evaluation.

Interpretation: As reported previously [7], all the patients with early removal because of serious adverse events made a full recovery and most derived considerable benefit despite the setback. Indeed, the mean HbA1c fall of 24.8 mmol/mol and weight loss of 13.6 kg from 114.9±22.8 to 101.3±22.8kg ($p<0.001$) are improvements experienced by the early removal group that were not greatly different from those of the full cohort [7]. The improvement in renal function associated with EndoBarrier induced weight loss is compatible with improvements in renal function associated with weight loss induced by bariatric surgery [13,14] and our results are in keeping with this additional benefit to patients over and above those previously reported for EndoBarrier. The potential impact of EndoBarrier on kidney function should be a focus for further evaluation. The development of renal impairment is associated with an over 5-fold increase in 10-year mortality risk in patients with Type 2 DM [15], and obesity is a major independent risk factor for accelerated progression of CKD [16].

EndoBarrier treatment requires only a relatively simple endoscopy procedure and it is noteworthy that endoscopy units and skilled endoscopists are ubiquitous throughout the NHS. In the context of the diabesity pandemic [17], there is a need for simpler treatments that are less invasive than bariatric surgery for the many patients with obesity and poorly controlled diabetes despite lifestyle and pharmaceutical interventions. Such patients are at very high cardiovascular risk [18-20] and our data suggests that EndoBarrier may reduce this risk [7]. These patients are also at high risk of the microvascular complications and it is well established that improving HbA1c and blood pressure, as EndoBarrier does in these patients, improves microvascular outcomes [21-24]. The benefits to the patients are particularly obvious when individual anecdotes are considered [25] (the patients on pages 12 and 13 in reference 25 are examples of patients who gained renal benefit). Follow up of our patients demonstrates maintenance of significant improvement one year after removal in 78% of cases for whom data were available [26]. Therefore, EndoBarrier deserves further investigation as potential treatment for wider use in uncontrolled diabesity, especially bearing in mind the cardiovascular and microvascular risk to these patients if they are not given additional treatment. The potential impact on renal function may also contribute to the potential for improved clinical outcomes.

Generalisability: Endoscopy units are ubiquitous throughout the NHS, as are skilled endoscopists. Patients with uncontrolled diabesity are also ubiquitous throughout the NHS and therefore it would be relatively easy to make EndoBarrier widely available. The lessons we have learned with regard to measures to minimise early removal for serious adverse events would also be useful to future services.

Acknowledgement

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Conflict of Interest

Dr Bob Ryder has received speaker fees, and/or consultancy fees and/or educational sponsorships from AstraZeneca, BioQuest, GI Dynamics, Janssen and Novo Nordisk. All other co-authors have nothing to declare.

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