

# Endoscopic proximal intestinal exclusion with Endobarrier bringing simultaneous benefit to both diabetes and obstructive sleep apnoea(OSA) requiring overnight continuous positive airway pressure ventilation(CPAP)- Case reports

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## Background

Obstructive sleep apnoea(OSA) is associated with obesity and any weight loss is known to improve OSA. Type 2 diabetes and OSA requiring continuous positive airway pressure(CPAP) are both conditions associated with obesity and independently associated with increased cardiovascular risk. Sometimes both conditions coincide in the same patient with, therefore, especially high cardiovascular risk.

Endobarrier is a relatively new device which has been proven to reduce weight and improve diabetes control in previous research trials. The Endobarrier is a 60cm long tube-like structure (open at both ends) composed of a fluoropolymer flexible wall and a crown-shaped anchor composed of a nickel-titanium alloy at one end. It is an endoscopically inserted device which is deployed in the small intestine (just beyond the stomach) and removed up to 1 year later.

## End OSA Trial

End-OSA trial (ISRCTN:33788132) is an NIHR sponsored research trial, to investigate to what extent does the weight loss associated with Endobarrier treatment improve the indices of OSA in patients with diabetes treated with CPAP(continuous positive airway pressure).

It is a response to intervention trial involving 18 subjects with study duration of 30 months and including patients with moderate OSA (Apnoea Hypopnea Index 15-29 events/hr) treated with CPAP, type 2 diabetes or prediabetes, obesity(BMI between  $\geq 30$  and  $\leq 45$  kg/m<sup>2</sup>) and age  $\geq 18$  years.

This ongoing study participants are recruited from sleep service clinic at City Hospital, Birmingham.

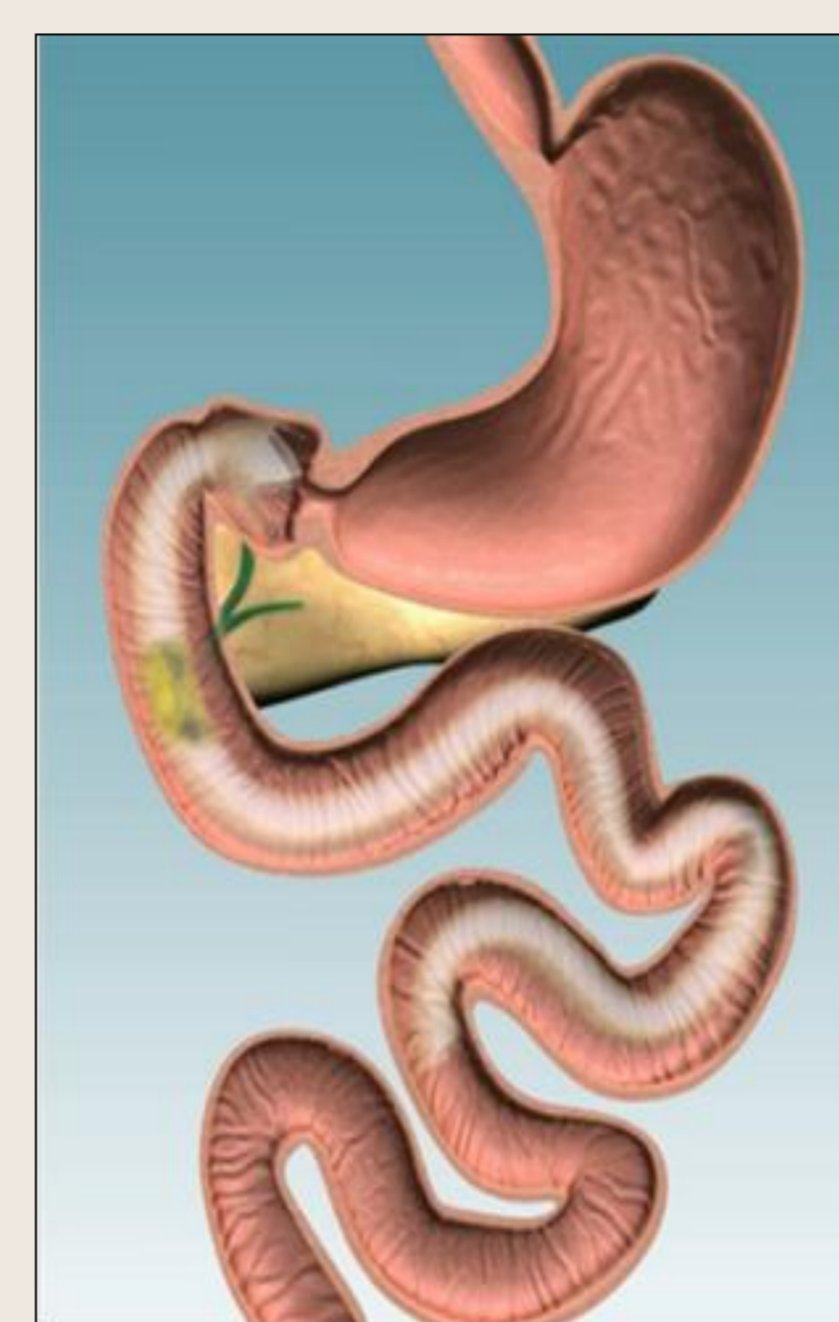
## Baseline Characteristics

	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6
Age(yrs)	58 (NHS)	61 (Trial)	59 (Trial)	49 (Trial)	30 (Trial)	53 (NHS)
Sex	F	F	F	F	F	M
Ethnicity	Caucasian	Caribbean	Caribbean	Caribbean	Caribbean	Caribbean
T2DM duration (yrs)	17	4	5	7	4	30
BL HbA1c (mmol/mol)	65	58	44	84	83	76
Baseline Wt(Kg)	86.6	84.4	110.1	96.6	98	116.4
BL BMI(Kg/m <sup>2</sup> )	35.2	33.5	39.5	33.3	37.3	38.0
Weight loss(kg)	21	12.4	1	7.6	8.0	28.4
Duration post Endobarrier (months)	12	6	3	3	3	12

## Results

**Case 1-** After 12 months of Endobarrier treatment, She has lost 21kg in weight and HbA1c fell to 43mmol/mol and BMI to 26.2kg/m<sup>2</sup> and she no longer required CPAP (NHS service patient).

### Endobarrier



### Case 1



**Case 2-** She was the first participant in End-OSA trial. This lady lost 12 kg after 6 months of endobarrier insertion(device still implanted), HbA1c fell to 44mmol/mol and she no longer required CPAP as confirmed on 3 monthly sleep studies.

**Case 3,4,5** – All part of End-OSA trial and within 3 months after the endobarrier treatment(device still implanted), their sleep studies have improved and suggested only mild OSA. They all have been advised to stop CPAP until their next 3 monthly assessment.

**Case 6** – This NHS service patient lost 28.4kg in weight and HbA1c fell to 49mmol/mol, BMI to 28.8kg/m<sup>2</sup>. He also had idiopathic interstitial pneumonitis requiring continual daytime ambulatory oxygen therapy but his symptoms of breathlessness had greatly improved and extensive investigation confirmed that the oxygen therapy was no longer required after Endobarrier treatment. He still on CPAP as his sleep studies suggest moderate OSA.

## Conclusion

These cases demonstrate that Endobarrier treatment benefits both diabetes and OSA. All patients achieved a substantial glycaemic control improvement, weight reduction and also reported considerable improvements in well-being and energy levels. As endoscopy units are ubiquitous Endobarrier treatment could be readily disseminated.