Endobarrier in Type 2 Diabetes/Pre-Diabetes with Obstructive Sleep Apnoea Study- Preliminary Results

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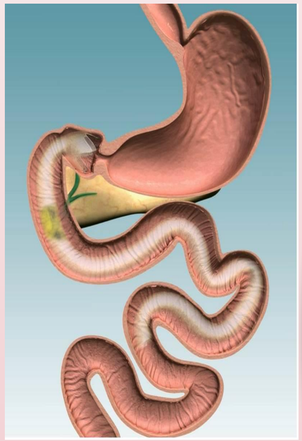
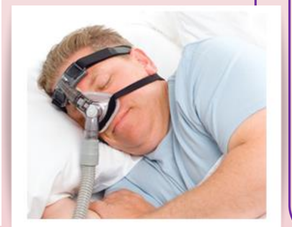
Background

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 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 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.



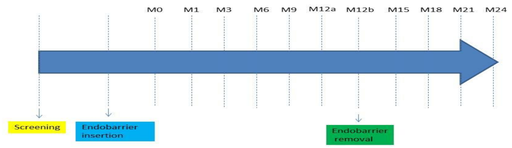


Aims

End-OSA trial (ISRCTN:33788132) is an NIHR sponsored research trial, to assess the extent to which patients with type 2 diabetes/pre-diabetes, obesity(BMI 30-45Kg/m²) and moderate OSA requiring CPAP are able to discontinue CPAP following endobarrier related weight loss.

It is a response to intervention trial involving 12 subjects with study duration of 24 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 ≥30 and ≤45 kg/m²) and age≥ 18years.

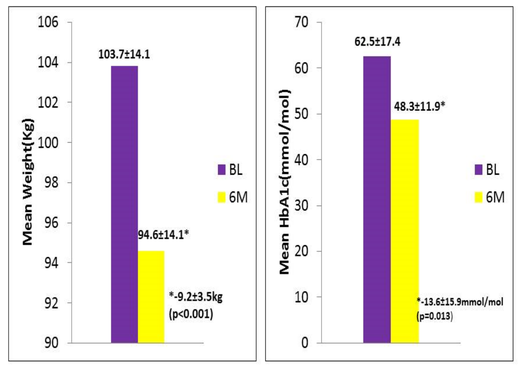
End-OSA Trial

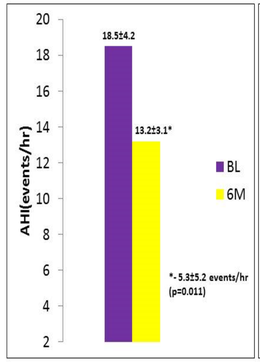


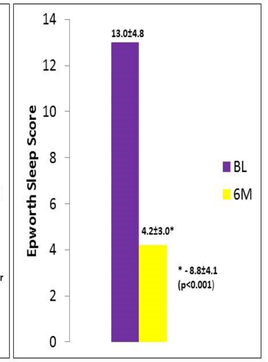
Baseline Characteristics

Age(years)	52.6±9.7
Sex(%)	Females(82%)
Ethnicity(%)	Caucasian(50%)
T2DM pt's (n)	8
Pre-diabetes pt's (n)	4
Mean Wt(kg)	103.8±14.1
Mean BMI(Kg/m²)	37.3±3.5
Mean HbA1c (mmol)	62.5±17.4
Mean AHI (events/hr)	18.5±4.2
Duration of OSA {Median(IQR)years}	1.5(1.0-2.4)

Results







Results

We report here the preliminary results of the 12 participants {9/12 (82%) female, 9/12 (82%) type 2 diabetes, 2/12 (18%) prediabetes, mean ± SD age 52.6±9.7 years} to reach at least 6 months of Endobarrier treatment. In those 6 months, weight fell by -9.2 ±3.5kg from 103.7 ± 14.1 to 94.6±14.1kg (p<0.001), mean BMI by -3.2±1.4kg/m² from 37.3 ±3.5 to 34.1 ±3.7kg/m² (p<0.001), mean HbA1c by -1.1±1.5%(13.6±15.9mmol/mol) from 7.8±3.8 to 6.5±3.7% (62.5±17.4 to 48.3±11.9mmol/mol (p = 0.013).

OSA improved by 5.34±5.2 events/hr from a baseline mean of 18.5±4.2 to 13.2±3.1 events/hr and Epworth sleep score fell from 13.0±4.8 to 4.2±3.1 (p<0.001).

Prior to Endobarrier treatment, all 12 patients had AHI in moderate sleep apnoea range (15-29.9 events/hour). Following Endobarrier treatment by 6 months, the AHI of 7/12(58%) patients fell below the moderate sleep apnoea threshold of 15 events/hour, such that they no longer required CPAP. Of the remaining 5 patients, 4 subjects came off CPAP at 9 months and the last one is due to have sleep studies at 6 months.

Conclusion

These preliminary results are encouraging in that Endobarrier has already allowed 11/12(91%) patients to discontinue CPAP, in addition to glycaemic and weight benefits.

Discontinuing CPAP is not only beneficial to health services but especially to patients. As endoscopy units are ubiquitous, Endobarrier treatment could be readily disseminated all over the NHS.

Sandwell and West Birmingham Hospitals NHS

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