Preliminary results of the Association of British Clinical Diabetologists sponsored Endobarrier in type 2 diabetes/pre-diabetes with obstructive sleep apnoea study

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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 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 ≥30 and ≤45 kg/m²) and age≥ 18years.

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

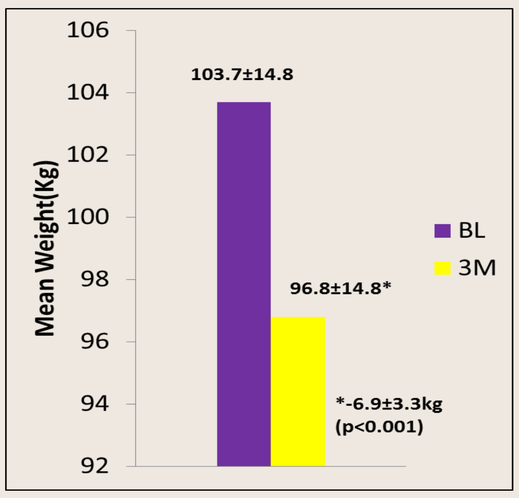
Baseline Characteristics

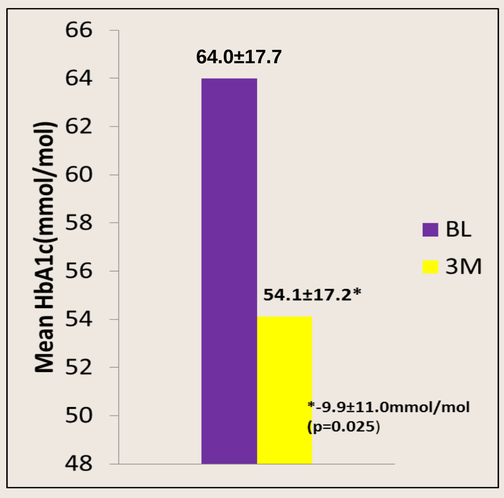
Age(years)	52.6±9.7
Sex(%)	Females(82%)
Ethnicity(%)	Caucasian(50%)
T2DM pt's (n)	9
Pre-diabetes pt's (n)	2
Mean Wt(kg)	103.7±14.8
Mean BMI(Kg/m²)	37.1±3.6
Mean HbA1c (mmol)	64.0±17.7
Mean AHI (events/hr)	19.1±3.8
Duration of OSA {Median(IQR)years}	1.5(1.0-2.4)

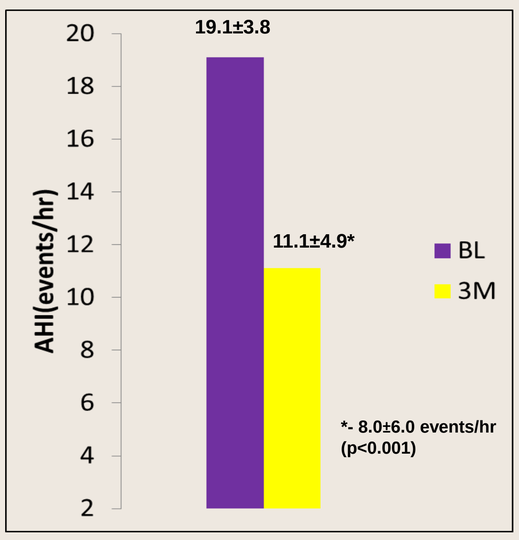
Endobarrier

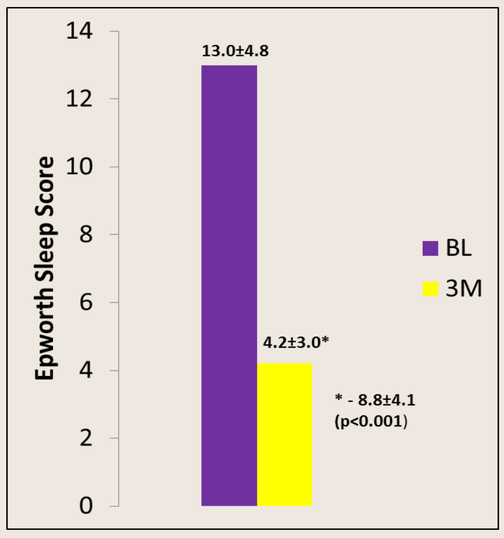
Results

We report here the results of first 11 participants who have reached 3 months of Endobarrier treatment. In 3 months, weight fell by 6.9 ± 3.3kg from 103.7 ± 14.8 to









96.8 ± 14.8kg (p<0.001), mean BMI by 2.5 ± 1.3kg/m² from 37.1 ± 3.6 to 34.6 ± 3.7kg/m² (p<0.001), mean HbA1c by 9.9±11.0mmol/mol from 64.0±17.7 to 54.1±17.2mmol/mol (p=0.025). During overnight sleep studies, three months after Endobarrier treatment, mean AHI(Apnoea Hypopnea Index) fell from 19.1±3.8 to 11.1±4.9 events/hour (p<0.001) and Epworth sleep score from 13.0±4.8 to 4.2±3.1 (p<0.001).

Prior to Endobarrier, all 11 patients had AHI in moderate sleep apnoea range (15–29.9 events/hour). Following Endobarrier, the AHI of 7/11(64%) patients fell below the moderate sleep apnoea threshold of 15 events/hour, such that they no longer required CPAP. Of the remaining 4 patients, 1 came off CPAP at 6 months**.** One of the participants had an SAE in the form of a small perforation of oesophagus during Endobarrier removal.

Conclusion

These preliminary results are encouraging in that Endobarrier has already allowed 8/11(73%) patients to discontinue CPAP, in addition to glycaemic and weight benefits. Discontinuing CPAP is beneficial to health services but especially to patients**.** As endoscopy units are ubiquitous, Endobarrier treatment could be readily disseminated all over the NHS.

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