Impact of Endobarrier on need for Continuous Positive Airway Pressure Ventilation(CPAP) in Diabetes/Pre-Diabetes with Obstructive sleep apnoea(OSA) study: Current data at Endobarrier removal and 6-months later

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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).

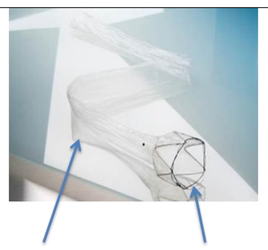
It is a response to intervention trial involving 12 subjects with study duration of 24 months including patients with moderate OSA (Apnoea Hypopnea Index 15-29 events/hr) treated with CPAP, type 2 diabetes or prediabetes, obesity(BMI between ≥30 and ≤45 kg/m²) and age≥ 18years.

This ongoing study participants are recruited from Birmingham's City Hospital sleep service clinic and all the clinic visits, blood tests as well as sleep studies are done at the same centre.

Baseline Characteristics

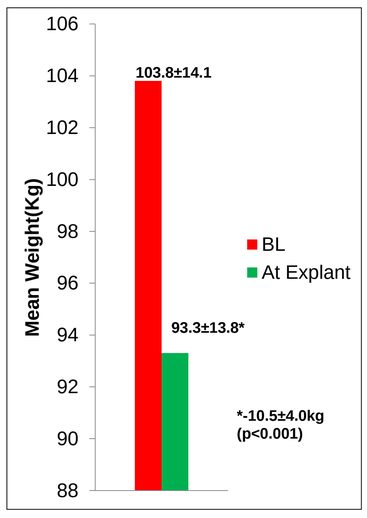
	n(12)
Age(years)	**52.6±9.7**
Sex(%)	**Females(75%)**
Ethnicity(%)	**Caucasian(50%)**
T2DM pt's (n)	**8(66%)**
Pre-diabetes pt's (n)	**4(33%)**
Mean Wt(kg)	**103.8±14.1**
Mean BMI(Kg/m²)	**37.4±3.5**
Mean HbA1c (%)	**7.9±1.7**
Mean HbA1c (mmol/mol)	**62.5±17.4**
Mean AHI (events/hr)	**18.8±3.8**
Duration of OSA {Median(IQR)years}	**1.5(1.0-2.4)**

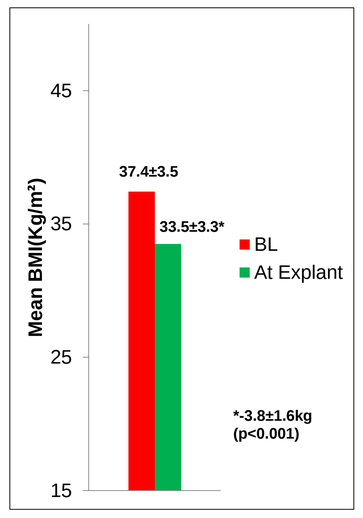
Endobarrier

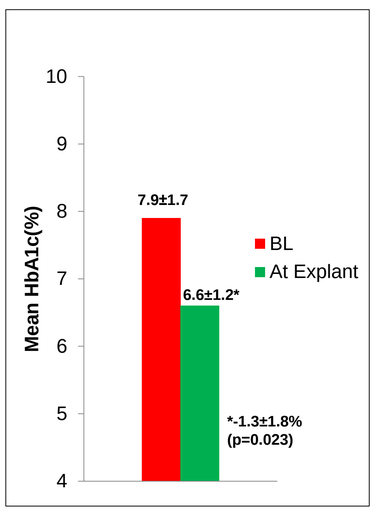


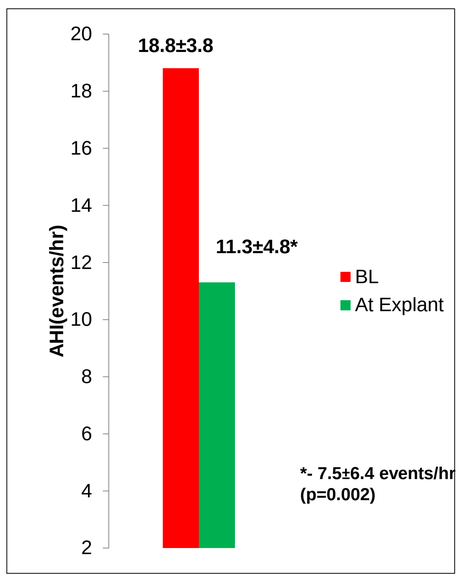
Results

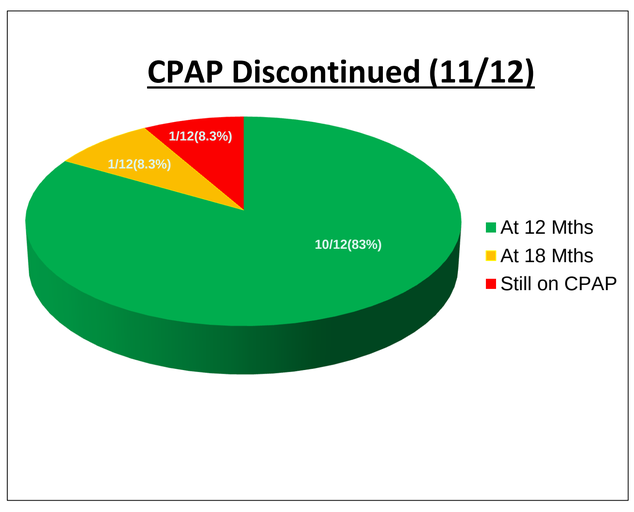
We report here the results on all 12 participants who have reached at least 12 months of Endobarrier treatment. At Endobarrier removal, the mean ± SD weight fell by 10.5 ± 4.0kg from 103.8 ± 14.1 to 93.3 ± 13.8kg (p<0.001),











mean BMI by 3.8 ± 1.6kg/m² from 37.4 ± 3.5 to 33.5 ± 3.3kg/m² (p<0.001), mean HbA1c by 1.3±1.8%(13.6±17.8mmol/mol) from 7.9±1.7%(62.5±17.4mmol/mol) to 6.6±1.2%(48.8±10.6mmol/mol) (p=0.023). In the follow up overnight sleep studies, twelve months after Endobarrier treatment, mean AHI(Apnoea Hypopnea Index) fell from 18.8±3.8 to 11.3±4.8 events/hour (p=0.002).

Prior to Endobarrier, all 12 patients had AHI in moderate sleep apnoea range (15–29.9 events/hour). But following Endobarrier treatment, the AHI of 10/12(83%) patients fell below the moderate sleep apnoea threshold of 15 events/hour, such that they no longer required CPAP, according to NICE guidelines. At follow up 6months after Endobarrier removal, all 6 patients who have so far attended, remained off CPAP with AHI<15 events/hour and also have persisting significant improvements in weight, BMI as well as HbA1c. One of the participants had an SAE in the form of a small perforation of oesophagus during Endobarrier removal which was conservatively managed.

Conclusion

These data demonstrate Endobarrier's effectiveness in allowing discontinuance of CPAP in moderate OSA, in addition to previously demonstrated glycaemic and weight benefits. Discontinuing CPAP is beneficial to health services but especially to patients.

Presented at 4th World Congress on Interventional Therapies for Type 2 Diabetes
8-10 April 2019 New York, USA

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