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Title: Electrical auricle stimulation device for obstructive and central sleep apnoea: A pilot study

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Body: Background: Severe obstructive (OSA) and central (CSA) sleep apnoea represent serious health consequences and are mostly treated by CPAP, but often perceived as uncomfortable. Long-term compliance for CPAP is low. Recently, an electrical auricle stimulation (EAS) device was developed to improve OSA as well as CSA. Methods: The EAS device applies an electrical stimulus to the auricle, at a low impedance point, upon cessation of breathing. The algorithm has an inbuilt stimulation delay of a few seconds. 40 male OSA/CSA patients were enrolled with broad selection criteria (BMI<40 kg/m^2). Nights with stimulation ON were compared to nights with stimulation OFF, with particular focus on changes in apnoea/hypopnoea index (AHI) and micro arousal index (ArI), based on attended polysomnography. Results: Stimulation for one night was efficacious (improvement of AHI ≥30%) in 18 out of 40 patients (from 47±20 to 22±15, p<0.01; -53%), followed by a trend towards a lower ArI (from 26±15 to 21±11, p=0.11). Accelerometry did not reveal unusual motion during stimulation ON. Responders reported to feel better or similar compared to CPAP treatment, while EAS was perceived as more comfortable. Baseline characteristics did not differ between responders and non-responders.

Table 1

	Responders**(N-18)		Non-Responders(N-22)	
Polysomnography results	AHI	ArI	AHI	ArI

Baseline	47±20	26±15	42±21	34±22
Stimulation	22±15*	21±11	45±22	34±20

*p<0.01 **AHI reduction ≥30% Mean±SD

Conclusion: EAS is feasible and allows treatment of OSA/CSA, without induction of arousals. Moreover, EAS is experienced as more comfortable than CPAP. Hence, these promising results warrant a prospective study to evaluate short- and long-term effects.