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Title: A randomized controlled study of upper airway stimulation therapy withdrawal effect in treatment of obstructive sleep apnea

Prof. Dr Patrick 571 Stollo stollopj@upmc.edu MD , Prof. Dr Ryan 572 Soose soosrj@upmc.edu MD and Prof. Dr Kingman 573 Strohl kpstrohl@aol.com MD . ¹ Medicine, University of Pittsburgh, Pittsburgh, PA, United States, 15213 ; ² Otolaryngology, University of Pittsburgh, Pittsburgh, PA, United States, 15213 and ³ Medicine, Case Western Reserve University, Cleveland, OH, United States, 44106 .

Body: Introduction: Upper Airway Stimulation is a promising treatment option for obstructive sleep apnea (OSA) patients. The primary aim of this randomized controlled trial was to determine the therapy withdrawal effect on polysomnographic (PSG) and quality of life (QOL) outcome measures. Methods: The STAR trial enrolled participants with moderate to severe OSA. Participants with BMI < 32 and without complete concentric collapse at the retropalatal airway received an implanted neurostimulator. After the 12 month follow-up, the withdrawal effect was assessed by randomizing consecutive therapy responders to one week of therapy suspension vs. maintenance followed by a PSG, and QOL measures including Epworth Sleepiness Scale (ESS) and Functional Outcomes of Sleep Questionnaire (FOSQ) Results: In the therapy ON (Tx ON) maintenance group, all outcome measures remained unchanged at one week. In the therapy OFF (Tx OFF) withdrawal group, all outcome measures returned towards baseline levels after one week (Table).

	Maintenance Group (n=23)			Withdrawal Group (n=23)		
	Baseline	Month-12	Tx ON	Baseline	Month-12	Tx OFF
AHI	28.7(12.3)	6.5(5.0)	7.0(9.1)	30.1(11.4)	7.6(4.0)	25.8(16.2)*
ODI	22.2(13.0)	4.9(5.4)	4.9(8.9)	26.8(10.2)	6.0(3.7)	23.0(15.6)*
FOSQ	15.3(2.9)	19.0(2.9)	18.8(2.9)	13.9(2.8)	17.0(3.5)	15.0(4.0)*
ESS	13.0(5.4)	5.0(3.4)	4.0(3.9)	11.2(5.4)	6.9(4.6)	10.0(6.0)*

Results in mean (SD), *p<0.05 Month-12 vs. Tx OFF

Conclusions: Acute withdrawal of therapy resulted in a return of OSA severity and a decline in quality of life measures compared to therapy maintenance after 12 months of upper airway stimulation treatment.

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