

**Title:** A novel hypoglossal nerve stimulation approach yields major improvements in airflow in people with obstructive sleep apnoea during propofol sedation

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**INTRODUCTION AND OBJECTIVES:** Hypoglossal nerve stimulation (HGNS) to treat obstructive sleep apnoea (OSA) currently requires placement of a cuff or 'saddle' electrode around or adjacent to the hypoglossal nerve(s). Limitations include cost, invasiveness, and variable efficacy. This proof-of-concept study aimed to determine the effect of a multi-pair HGNS electrode array implanted via a relatively simple percutaneous approach on airflow.

**METHODS:** People with OSA were instrumented an epiglottic pressure catheter, nasal mask and pneumotachograph to quantify airflow. The hypoglossal nerve was identified via ultrasound to guide percutaneous electrode array placement following propofol sedation. A modified CPAP device delivered therapeutic CPAP. Transient CPAP reductions were then applied to induce airflow obstruction for  $\geq 9$  breaths/efforts where HGNS was applied during breaths 4-6. A range of HGNS amplitudes (0.5-5mA) and electrode array combinations were tested during an  $\sim 1.5$ h protocol to determine optimal airflow response to HGNS.

**RESULTS:** We studied 14 people with severe OSA (mean $\pm$ SD AHI=30 $\pm$ 16events/h). 13/14 had an increase in airflow at the optimal stimulation setting and location. Average peak inspiratory flow (PIF) on therapeutic CPAP was 0.38 $\pm$ 0.10 L/s<sup>-1</sup>. During the 9 breath/effort transient CPAP reductions, PIF was reduced to an average of 0.12 $\pm$ 0.07 L/s<sup>-1</sup> for breaths 1-3 (p<0.01 vs. therapeutic CPAP) and increased to therapeutic CPAP levels with HGNS for breaths 4-6 (0.43 $\pm$ 0.17L/s<sup>-1</sup>, p=0.38 vs. therapeutic CPAP) and returned to 0.15 $\pm$ 0.14 L/s<sup>-1</sup> for breaths 7-9 upon HGNS cessation.

**CONCLUSIONS:** Acute HGNS via a novel, less-invasive, percutaneous ultrasound-guided stimulation array in people with severe OSA markedly improves airflow, equivalent to therapeutic CPAP levels.