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Newer **R**esearch and recommendations **I**n **C**hild **H**ealth

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Upper-Airway Stimulation for Obstructive Sleep Apnea

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BASED ON ARTICLE

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SUMMARY

Background: Patients with moderate-severe OSA require night-time CPAP. However CPAP is not always tolerated well, and adherence is often poor. This study evaluated the clinical safety and effectiveness of upper-airway stimulation for 12 months for the treatment of moderate-to-severe obstructive sleep apnoea in patients not adhering or tolerating CPAP.

This is a relatively old study but assumes significance now as this modality of treatment has been approved in March 2023 by the FDA for treatment of children 13 years and above , with Down syndrome.

Methods-Using a multicentre, prospective, single-group, cohort design, they surgically implanted an upper-airway stimulation device in adult patients with obstructive sleep apnoea who had difficulty either accepting or adhering to CPAP therapy. Patients were selected after performing polysomnography, medical and surgical consultation and endoscopy was done during drug induced sleep. Patients with AHI less than 20 and more than 50 per hour were excluded. Participants were also excluded if pronounced anatomical abnormalities preventing the effective use or assessment of upper-airway stimulation were identified during the surgical consultation (e.g., tonsil size of 3 or 4) or if complete concentric collapse at the retropalatal airway was observed on endoscopy performed during drug-induced sleep.

Qualified participants underwent a surgical procedure to implant the upper-airway stimulation system (Inspire Medical Systems)

The implant consists of sensing lead in intercostal muscles to sense the ventilation and the stimulating lead is attached to medial branch of hypoglossal nerve. The neurostimulator is placed in the right infraclavicular area. .The participants had their device activated and were instructed regarding the use of a controller to initiate and terminate therapy on a nightly basis. The neurostimulator activates the genioglossus muscle, resulting in tongue protrusion. One month after the implantation, PSG was repeated, and implant was activated.

The primary outcome measures were the apnoea–hypopnea index (AHI; the number of apnoea or hypopnea events per hour, with a score of ≥15 indicating moderate-to-severe apnoea) and the oxygen desaturation index (ODI; the number of times per hour of sleep that the blood oxygen level drops by ≥4 percentage points from baseline). Secondary outcome measures were the Epworth Sleepiness Scale, the Functional Outcomes of Sleep Questionnaire (FOSQ), and the percentage of sleep time with the oxygen saturation less than 90%. One year after implantation, Polysomnography was repeated and response to treatment was documented. Consecutive participants with a response were included in a randomization and half the patients were subjected to therapy withdrawal and one-week later PSG was done to document AHI.

Results : The study included 126 participants; 83% were men. The mean age was 54.5 years, and the mean body-mass index was 28.4. The median AHI score at 12 months decreased 68%,from 29.3 events per hour to 9.0 events per hour (P<0.001). The ODI score reduced 70% from 25.4 events per hour to 7.4 events per hour (P<0.001). Secondary outcome measures showed a reduction in the effects of sleep apnoea and improved quality of life. 83 patients showed response to treatment. In the randomized phase, 46 consecutive patients were enrolled. The mean AHI score did not differ significantly from the 12-month score in the randomized phase among the 23 participants in the therapy-maintenance group (8.9 and 7.2 events per hour, respectively). The AHI score was significantly higher among the 23 participants in the therapy-withdrawal group (25.8 vs. 7.6 events per hour, P<0.001). The ODI results followed a similar pattern. The rate of procedure-related serious adverse events was less than 2%.

Conclusions:In this uncontrolled cohort study, upper-airway stimulation led to significant improvements in objective and subjective measurements of the severity of obstructive sleep apnoea.

COMMENTARY

Obstructive sleep apnoea is narrowing or closure of airway during sleep resulting in fall in the level of oxygen in blood. OSA is associated with risk of hypertension, diabetes mellitus, dyslipidaemia, pulmonary hypertension. Moderate-severe obstructive sleep apnoea is defined as Apnoea- hypopnea index (AHI) of 15 or more events per hour in adults and more than 5 in children. Treatment of OSA includes night-time CPAP. Sleep apnoea can be due to obstructive cause, central cause, or both. Anatomical factors, obesity, craniofacial syndromes, neuromuscular disorders contribute to sleep apnoea. In children with sleep apnoea, the first line treatment is treatment of adeno-tonsillar hypertrophy. If the child continues to have persistent OSA, CPAP is instituted. CPAP therapy requires desensitization and acclimatisation to the mask and pressure. In children adherence to therapy and acceptance is far less than adults. In very young children availability of appropriate size mask is also difficult.

In the above study, only adult patients were selected and patients with anatomical abnormalities, and other confounding comorbid conditions were excluded. Patients with retropalatal concentric airway collapse were excluded.

The implant is inserted surgically, and the sensing lead is in the intercostal muscles and the stimulating lead is placed in the hypoglossal muscle. On activation of device during bedtime the hypoglossal muscle contracts synchronous with ventilation, resulting in protrusion of tongue in inspiration. This helps in opening of upper airway. The careful selection of patient is necessary as few patients in the above study did not respond to treatment or worsened with this therapy. In patients with OSA with central cause or mixed type have hypoventilation, CPAP or BiPAP is preferred. Hence during PSG, when central or mixed cause of hypoventilation present more than 25% of events, they are not the candidates for this implant. Children with upper airway collapse, responding to tongue protrusion are the ideal candidates for this implant. Children with obesity, craniofacial syndromes, down syndrome, achondroplasia can be tested with this implant after ruling out central cause of hypoventilation. Upper airway stimulation can become the third line of treatment before surgery like uvulopalatopharyngoplasty.

The safety, adverse effects and efficacy of the implant needs to be verified with RCT in adults before trying in young children. The above procedure requires surgery and hence non-invasive treatment need to be initiated and non-responders and patients with difficulty on adhering to CPAP can be tried with surgical options like- upper airway stimulation implant.
Upper airway stimulation is a novel way of opening of upper airway and has the potential to become as one of the treatment modalities in future with children with obstructive sleep apnoea, not adhering to CPAP.

As of March 21. 2023, the FDA. has approved this form of therapy for OSA patients with Downs syndrome who are at least 13 years old, with an AHI between 10 and 50 and are not suitable for CPAP. Hence practising Paediatricians should be aware of this alternative -as the scope and ambit of this therapy is likely to increase over time.