

Tongue stimulation device reduces sleep apnea in adolescents with Down syndrome

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A surgically implanted device that moves the tongue forward during sleep was found to safely and effectively reduce sleep apnea in adolescents with Down syndrome, according to a new study published

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Children with Down syndrome are significantly more likely to have obstructive [sleep apnea](#) and current treatment options are often ineffective. The implantable pacemaker-like device, called a hypoglossal nerve stimulator, may offer a new treatment option for this medically underserved population, according to the study's authors. They plan to build upon the findings and test the treatment in additional clinical trials looking at outcomes including improvements in neurocognition and language ability.

"This study was born out of the frustration of not having an effective treatment option for [children](#) with Down Syndrome who struggle with sleep [apnea](#)," said lead study author Christopher Hartnick, MD, MS, director of the Division of Pediatric Otolaryngology and the Pediatric Airway, Voice and Swallowing Center at Mass Eye and Ear, and professor of Otolaryngology–Head and Neck Surgery at Harvard Medical School. "Sleep apnea significantly impacts these children, often affecting their language, behavior and ability to do well in school. Any diminishment in these areas is critical for families, and our study suggests we may finally have an option to help."

Sleep apnea's disproportionate impact on Down syndrome community

Pediatric obstructive sleep apnea occurs when a child's airway is blocked during sleep, causing snoring, difficulty breathing and restless sleep. For any child, it can result in [daytime sleepiness](#), behavioral issues and learning challenges.

However, the condition is particularly prevalent in children with Down syndrome: About 80 percent of children with Down syndrome have

obstructive sleep apnea, compared to 5 percent of the general pediatric population. Children with Down syndrome and sleep apnea are more likely to experience aggressive behavior, brain fogging and a loss of nearly 10 points in IQ compared to those without.

Surgery to remove the adenoids and tonsils is the traditional first-line treatment option for opening the airway, but studies have shown less than 30 percent of children with Down syndrome benefit from the procedure. Experts believe this may be because children with Down syndrome are more likely to have a larger tongue. Another procedure, a tongue base surgery, can be painful with limited evidence of effectiveness. What's more, children with Down syndrome often have difficulty adhering to [continuous positive airway pressure](#) (CPAP) therapy due to sensory difficulties.

Upper airway stimulation using a hypoglossal nerve stimulator is a well-studied sleep apnea treatment in adults who can't tolerate CPAP therapy. The hypoglossal nerve stimulator is a Food and Drug Administration-approved device that is surgically implanted in an outpatient setting. When the device senses someone trying to take a breath, it sends an electrical pulse to the hypoglossal nerve that controls the tongue, causing it to move forward in the mouth, thereby opening the airway.

Testing device for safety and efficacy

This phase I clinical trial was the first to test the device in a pediatric population with Down syndrome.

In the study, 42 adolescents with Down syndrome and severe [obstructive sleep apnea](#) between the ages of 10 and 22 were recruited across five U.S. medical centers. They all underwent surgery to implant the hypoglossal nerve stimulator and were tracked for one year.

The researchers measured participants' apnea-hypopnea index (AHI), which is a measurement used to indicate severity of sleep apnea by counting the number of apnea events per hour during a sleep study. In children, an AHI of 0-to-1 is normal, 1-to-5 is mild sleep apnea, 6-to-10 is moderate and anything more than 10 events per hour is considered severe.

At one year follow-up, 27 patients (66 percent) responded well to treatment; the AHI of these patients decreased by at least 50 percent. On average, the patients reduced their AHI by 12.9 events per hour following treatment, a drop of more than 51 percent. Following treatment, 30 patients (73.2 percent) had an AHI under 10 events per hour, 14 patients (34.1 percent) had an AHI under 5 events per hour, and three patients (7.3 percent) had an AHI under 2 events per hour.

Quality-of-life surveys filled out by parents reported significant improvements in daily functioning, behavior and language.

The procedure was also found to be safe overall. The most common adverse event was tongue discomfort in five patients, which typically resolved in weeks.

According to the researchers, the findings move them closer towards their goal of providing enough data to the FDA to approve the indication of this device for children younger than age 18 with Down syndrome.

"Sleep apnea remains one of the most common conditions that I grapple with working with patients with Down syndrome and their families," said study co-author Brian Skotko, MD, MPP, the Emma Campbell Endowed Chair on Down Syndrome at Massachusetts General Hospital. "Until now, so many of our patients had run out of treatment options, and their health and well-being were declining. Now, with the hypoglossal nerve stimulator treatment, we may have an effective and

safe way to treat apnea and maximize brain health for people with Down syndrome."

Findings fuel further study

The new research lays the groundwork to conduct further studies. According to Dr. Hartnick, the findings raise a need for looking at additional outcome measures besides AHI. Even children who had an AHI reflecting moderate to severe [sleep](#) apnea after surgery still reported quality-of-life improvements, which suggests neurocognition might be a more appropriate outcome to study, he said.

"Although our results were compelling, it revealed that we need to carefully look at what other outcome measures we're using," said Dr. Hartnick. "That's what our next study is looking for."

Dr. Hartnick and Dr. Skotko received a \$4 million, five-year grant from the National Institutes of Health (NIH) in January 2021 to study if upper airway stimulation might improve neurocognition and language in [young patients](#) with Down syndrome.

"When parents reported anecdotally that the implant seemed to improve speech in their loved ones, we knew that we needed to investigate this further," added Dr. Skotko. "The NIH grant will enable us to formally analyze improvements that the implant may or may not have on speech and cognition."

More information: Evaluation of Upper Airway Stimulation for Adolescents With Down Syndrome and Obstructive Sleep Apnea, *JAMA Otolaryngology–Head & Neck Surgery* (2022). [DOI: 10.1001/jamaoto.2022.0455](#)

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