Trigeminal nerve stimulation may be an effective non-drug treatment for ADHD

A team at the University of California at Los Angeles (UCLA) has just reported on the first-ever, double-blinded, sham-controlled study of trigeminal nerve stimulation (TNS) for treating ADHD. The trigeminal nerve is the largest cranial nerve. It enables facial sensation, as well as biting and chewing.

Over a four-week period, researchers fitted 62 eight-to-twelve-year-old children with electrodes while they slept; 32 got an active low current, the rest none at all. The active and sham setups were identical in appearance. The children were told, "pulses may come so fast or so slowly that the nerves in the forehead might or might not detect a sensation." At the conclusion of the four weeks, there was an additional blinded week without intervention.

The primary efficacy outcome measure was the clinician-completed ADHD-RS total score, derived from parent interviews and available clinical information. It was completed at the onset of the study, and repeated over subsequent weeks. The Clinical Global Impression (CGI) score was used as a secondary outcome measure.

Both groups of children showed significant reductions in ADHD symptoms over the first week. But scores leveled off during the remaining three weeks for the group with sham treatment, while scores continued to decline for those in the group with actual stimulation. The standardized mean difference (SMD) between groups was 0.5.

By the conclusion of week 4, 52 percent for those in active treatment were improved or very much improved as indicated by CGI scores; only 14 percent did as well with the sham treatment. The number needed to treat was just 3.

After discontinuation of treatment, total scores in both groups rose at similar rates. At the end of week 5, CGI ratings for active treatment showed 13 percent improvement over baseline, versus 7 percent for sham treatment. The SMD was 0.46, once again indicating persistence of a medium effect size a week after treatment cessation.

The effect sizes computed for TNS are roughly comparable to effect sizes for nonstimulant medication, but less than those for stimulants.

Though the active group had significant gains in weight and pulse over the sham group, there were no serious adverse events in either group.

The authors concluded: "Results from the Early Impressions Questionnaire showed no differences in outcome expectations between treatment groups after 1 week using the randomized device, suggesting that our sham procedures successfully accomplished double blinding of group assignment. Improvements seen in the active and sham groups at week 1 likely reflect some placebo response secondary to the high level of parental involvement in administering treatment. Nonetheless, further improvement over subsequent weeks with active TNS suggests the emergence of true treatment effects … TNS is a non-medication minimal risk intervention with proven efficacy in alleviating ADHD symptoms. Although the present study finds that only slightly more than half of those receiving therapy have clinically meaningful improvement, the virtual lack of significant side effects should make it a popular treatment choice for many patients with ADHD, particularly for parents who prefer to avoid psychotropic medication."

Nevertheless, one must keep in mind that this is a single un-replicated study with a small sample size. Further studies with larger numbers of participants are needed, both to confirm efficacy and to further explore the weight gains and higher pulse rates in the treatment group.

REFERENCES

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