Drug used to treat daytime sleepiness does not appear to improve driving in those with sleep apnea

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In "Does Armodafinil Improve Driving Task Performance and Weight Loss in Sleep Apnea? A Randomized Trial," Nathaniel Marshall, Ph.D., and his colleagues at the Woolcock Institute for Medical Research, University of Sydney, report on their study of armodafinil, which has been approved by the U.S. Food and Drug Administration to treat excessive daytime sleepiness due to OSA, narcolepsy and other conditions.

The researchers found that armodafinil did not improve the driving

performance of those with OSA after six months of use, the study's primary outcome. Nor did those taking the drug report less daytime sleepiness than those receiving a placebo, as measured by the Epworth Sleepiness Scale and the Functional Outcomes of Sleep Questionnaire.

In the study, 113 participants (ages 18 to 70) were randomly assigned to either receive 150 mg of armodafinil daily or a placebo. Participants had moderate to severe OSA, were moderately obese and did not use continuous positive airway pressure (CPAP) or an oral appliance that advances their lower jaw. Both therapies treat OSA by preventing the pauses in breathing that occur in OSA when the back of the throat collapses.

All participants were also randomly assigned to one of two popular diets in Australia: the Australian Guide to Healthy Eating diet, which is similar to the American Dietary Guidelines "Choose My Plate," or a low-glycemic index, high-protein diet. Driving ability was assessed during a simulated 90-minute drive.

According to Dr. Marshall, a clinical trials epidemiologist, about half of patients seen in sleep clinics fall into the category of having sleep apnea and abdominal obesity but being unable to tolerate CPAP or an oral appliance. "My clinical colleagues and I call these patients the 'forgotten patients,'" he said. "We felt we needed to help our patients lose weight to address their metabolic risks over the longer term whilst addressing their sleepiness and neurocognitive dysfunction immediately with armodafinil."

He added that sporadic reports indicate that patients using armodafinil and its cousin modafinil to improve wakefulness experienced weight loss, so he and his coauthors wanted to test whether the drugs might increase the success of a deliberate weight loss program.

In the current study, armodafinil did, in fact, have a positive effect on body mass. Participants on the drug lost more body fat on either of the diets, which appeared to reduce weight equally well, than those who received the placebo. At six months, those in the armodafinil arm of the study lost an average of 6.4 pounds more body fat than those receiving the placebo. The researchers said that some of this additional weight loss may be due to the increased activity levels of those receiving the drug, as measured by an activity tracker. Importantly, the authors noted that armodafinil did not appear to increase blood pressure.

Armodafinil also appeared to improve driving ability after three months. The researchers speculate that those taking armodafinil learned their simulated driving tasks faster than those receiving the placebo because by six months there was no difference between the two groups. Even with the improvements that came with practice, the authors noted that, on average, driving ability among these participants with untreated OSA was two standard deviations worse than healthy people without OSA.

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