Obstructive Sleep Apnea and Obesity Treated with Tirzepatide

Researchers investigated the effects of tirzepatide on adults with obesity and moderate-to-severe obstructive sleep apnea (OSA).

They found that tirzepatide significantly reduced the apnea-hypopnea index (AHI), body weight, concentration of high-sensitivity C-reactive protein (hsCRP), hypoxic burden, and systolic blood pressure (SBP), and improved patient-reported sleep-related outcomes compared to placebo.

Study

The SURMOUNT-OSA trials consisted of two phase III, double-blinded, randomized controlled studies conducted between June 2022 and March 2024 across 60 sites in nine countries, aimed at evaluating the safety and efficacy of tirzepatide in adults with moderate-to-severe OSA (AHI ≥15 events per hour) and obesity (BMI ≥30 or ≥27 in Japan).

Trial 1 included participants not able or not willing to use PAP therapy, while trial two involved participants using PAP therapy for at least three months. Participants with type 1 or 2 diabetes, recent significant weight change, planned surgery for sleep apnea or obesity, major craniofacial abnormalities, and central or mixed sleep apnea were excluded.

In trials 1 and 2, the participants had a mean age of 47.9 and 51.7 years, respectively. A majority of the participants were male (67.1%, 72.3%) and White (65.8%, 73.1%).

After screening for four weeks, participants were assigned to trial 1 (n = 234) or trial 2 (n = 235) and randomly given tirzepatide or placebo once weekly for 52 weeks.

The primary endpoint was the alteration in AHI from baseline. Secondary endpoints included percent change in AHI, reduction in AHI by at least 50%, achieving AHI of > five events per hour, change in body weight, hsCRP concentration, hypoxic burden, PROMIS (short for patient-reported outcomes measurement information system) scores for sleep disturbance (PROMIS-SD) and sleep-related impairment (SRI), and SBP.

Adverse and serious adverse events were monitored throughout the reporting period. Statistical analysis involved treatment-regimen and efficacy estimands, analysis of covariance, logistic regression, and multiple imputations for missing data.

Findings and Discussion

The trials showed a high completion rate (82.9%) and high overall adherence (79.7%). Estimand analysis showed that tirzepatide treatment significantly reduced the AHI as compared to the placebo in both trials ($p<0.001$).

Additionally, participants on tirzepatide showed improvements in sleep apnea-specific hypoxic burden, and more than 50% achieved clinically meaningful reductions in AHI.

Further, participants who received tirzepatide in both trials 1 and 2 experienced significant reductions in PROMIS-SRI and PROMIS-SD T scores as well as body weight, systolic blood pressure, and hsCRP concentration.

No deaths were reported during the trials. However, participants receiving tirzepatide reported higher rates of gastrointestinal adverse events, with two cases of acute pancreatitis in trial 2.

The trials are strengthened by their global nature, adequate size, significant representation of women, assessment of multiple relevant endpoints, and generalizability, and provided insights into tirzepatide's effects in patients with and without current PAP therapy.

However, the limitations of the trials include their short duration, exclusion of non-obese participants, lack of analysis on PAP adherence, unexamined symptom presence at baseline, undefined clinical importance for PROMIS measures, and assessment only up to 52 weeks of treatment.

Conclusion

In conclusion, in the two trials, tirzepatide was found to bring about a clinically significant improvement in sleep-disordered breathing, sleep disturbance, and sleep-related impairment while reducing OSA-related cardiovascular risk factors, including AHI, body weight, hypoxic burden, hsCRP concentration, and SBP in individuals with moderate-to-severe OSA and obesity.

These results highlight tirzepatide's potential as a treatment option for improving sleep-related outcomes in this population.

Source:

https://www.news-medical.net/news/20240626/New-drug-tirzepatide-significantly-improves-sleep-apnea-and-weight-loss.aspx