Increased risk of hearing impairment with new thyroid eye disease treatment

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More patients than previously reported may experience hearing symptoms such as hearing loss or muffled hearing from a new treatment for thyroid eye disease, teprotumumab (Tepezza), according to a small study presented virtually at ENDO 2021, the Endocrine Society's annual meeting.

Teprotumumab, approved by the U.S. Food and Drug Administration in January 2020, is the first and only drug to be approved for thyroid eye disease. In two clinical trials conducted prior to FDA approval of the drug, otologic symptoms were reported in 10 percent of patients. The new study found the rate could be as high as 65 percent.

The treatment is administered to patients once every three weeks for a total of eight infusions. It has shown significant improvement in abnormal protrusion of the eyes (proptosis), double vision, soft tissue inflammation and quality of life.

Andrea Lora Kossler, M.D., assistant professor of ophthalmology at the Stanford University School of Medicine, is the senior author on the research. She and fellow researchers state that teprotumumab is an effective therapy for thyroid eye disease, but as with all therapeutics, there are known risks, including hearing impairment. The authors aim to better understand the risk of hearing loss and recommend tests to reduce this risk.

Thyroid eye disease is an autoimmune disease in which the eye muscles and fatty tissue behind the eye become inflamed. Symptoms can include dry, watery, red or bulging eyes, a "stare," double vision, difficulty closing the eyes, and problems with vision. It is primarily associated with an overactive thyroid gland due to Graves' disease.

To explore the incidence of hearing symptoms in patients treated with teprotumumab, the researchers evaluated 26 patients treated with at least four infusions of the drug. Seventeen patients (65 percent) complained of otologic symptoms when questioned. The most common symptoms were subjective hearing loss (n=6, 23 percent), tinnitus, or ringing in the ears (n=7, 27 percent), ear plugging sensation (n=3, 12 percent), and autophony, an unusually loud hearing of a person's own voice (29 percent). Otologic symptoms developed after an average of 3.6 infusions.

Of the 17 patients with new hearing symptoms, four had new or worsening sensorineural hearing loss, a type of hearing loss resulting from damaged hair cells in the inner ear. Three patients had patulous eustachian tube, a disorder in which the channel that runs between the middle ear and back of the nose and throat stays open. Normally, these eustachian tubes remain closed and open only occasionally to regulate air pressure around the ear drum. After three months, symptoms of patulous eustachian tube improved, but did not completely disappear. Two patients with sensorineural hearing loss had improvement in symptoms at one and six months.

The authors aim to raise awareness on the incidence of otologic symptoms & recommend screening precautions, such as baseline audiogram testing to better understand this potential side effect. The follow up period of 3 months after stopping the drug is too short to assess the reported reversibility of otologic symptoms. Future studies will evaluate risk factors for hearing loss and the reversibility of symptoms.

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