Ear Tubes Can Be Inserted With Local Anesthesia

A recently approved device will enable young children who need tympanostomy tubes for otitis media to have them inserted with local anesthesia in a physician’s office. Traditionally, children who needed the ear tubes underwent surgery requiring general anesthesia in a hospital or surgical center.

According to the National Institute on Deafness and Other Communication Disorders, 5 of every 6 children will develop at least 1 ear infection by their third birthday. “As millions of children suffer from ear infections every year, it is important to have safe and effective treatments available to this susceptible patient population,” Jeff Shuren, MD, director of the FDA’s Center for Devices and Radiological Health, said in a statement.

The Tubes Under Local Anesthesia (TULA) system was approved for adults and children as young as 6 months old. It’s an iontophoresis system that uses a small amount of electrical current to quickly anesthetize the tympanic membrane. Once it’s numb, the delivery system makes a small incision and inserts the tube in less than 500 milliseconds, according to a statement from the manufacturer, Tusker Medical Inc of Menlo Park, California.

To evaluate the system, the FDA reviewed data provided by Tusker Medical from 222 pediatric patients who underwent ear tube insertion with the TULA system. The agency reported that the system successfully inserted ear tubes in 86% of children younger than 5 years and in 89% of children aged 5 to 12 years. The most common adverse event was inadequate anesthesia during the procedure.

The system should not be used in children younger than 6 months or in patients with allergies to some local anesthetics. It’s also not intended for patients who may have preexisting eardrum problems.

New Option for Sickle Cell Disease

The FDA has boosted treatment options for sickle cell disease by approving voxelotor for adults and adolescents aged 12 years or older who have the illness.

Marketed as Oxbryta, the drug “is an inhibitor of deoxygenated sickle hemoglobin polymerization, which is the central abnormality in sickle cell disease,” Richard Pazdur, MD, director of the FDA’s Oncology Center of Excellence, said in a statement. When patients take the medication “sickle cells are less likely to bind together and form the sickle shape, which can cause low hemoglobin levels due to red blood cell destruction,” Pazdur added.

Current treatments for sickle cell disease include the anticancer drug hydroxyurea, which increases fetal hemoglobin levels and decreases the frequency of painful episodes. In 2017, the FDA approved L-glutamine oral powder, an amino acid that helps prevent sickle red blood cells from sticking to endothelial cells in blood vessels. The only known cure is a bone marrow transplant, but it requires a matched donor and can cause severe adverse events. About 100 000 people in the United States have sickle cell disease, according to the FDA.

Voxelotor’s approval was based on results from a phase 3 trial involving 274 patients with sickle cell disease. Most had anemia and were taking hydroxyurea at baseline. They were randomized to receive a higher or lower dose of voxelotor or placebo. After 24 weeks, 51% of patients in the higher-dose group had a hemoglobin response—a hemoglobin increase of more than 1.0 g/dL of blood—compared with 33% in the lower-dose group and 7% in the placebo group. Fewer patients in both treatment groups had acute anemic episodes compared with the placebo group.

The most common adverse events in the trial were headache, diarrhea, nausea, and arthralgia.

Novel Alternative for Partial-Onset Seizures

The novel antiepileptic medication cenobamate has received approval for adults who have partial-onset seizures. The drug offers a new alternative for the more than one-third of patients with epilepsy whose seizures aren’t controlled despite treatment with 1 or more antiepileptic drugs.

Marketed as Xcopia, cenobamate is a tetrazole alkyl carbamate derivative that has shown broad anticonvulsant activity in preclinical epilepsy studies. It’s been evaluated in 2 clinical trials, involving 222 patients that remains ongoing.

In the other trial, 437 patients were randomized to receive 100 mg, 200 mg, or 400 mg of cenobamate or placebo. The study was designed with a 6-week titration phase and a 12-week maintenance phase. At the end of the 18 weeks, seizure frequency was reduced by 24% in the placebo group, 35.5% in the 100-mg group, and 55% in both the 200-mg and 400-mg groups. In addition, the proportion of patients whose seizure frequency decreased by 50% or more during the maintenance phase was 25% in the placebo group, 40% in the 100-mg group, 56% in the 200-mg group, and 64% in the 400-mg group.

Common adverse events include somnolence, dizziness, fatigue, double vision, and headaches. Investigators for the published trial also reported that 3 patients who received cenobamate developed hypersensitivity reactions. – Rebecca Voelker, MSJ

Note: Source references are available through embedded hyperlinks in the article text online.