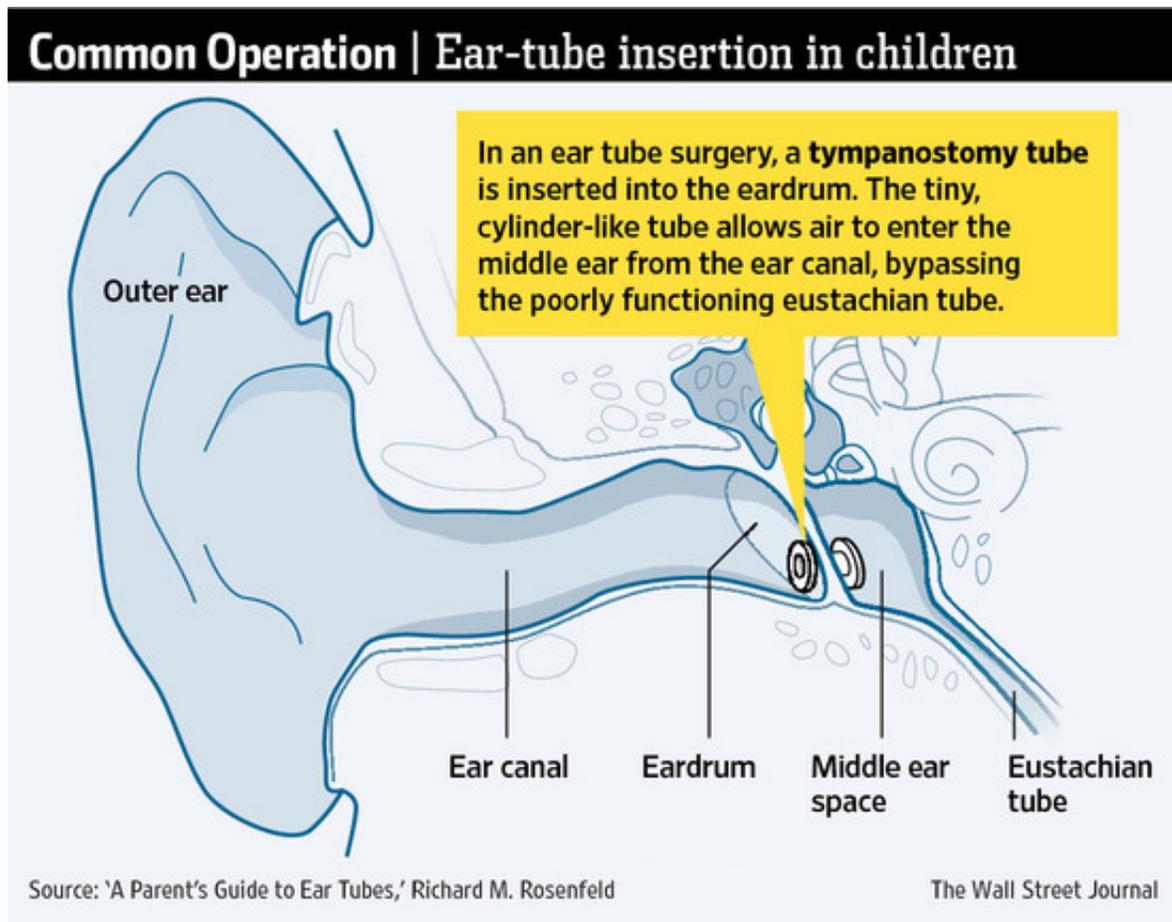


Effort Seeks to Reduce Ear-Tube Surgeries for Small Children

June 16, 2014 7:03 p.m. ET



Parents of young, otherwise healthy children fear them like the plague: ear infections.

The infections can lead to the most-common surgery done with anesthesia in young children. Some 667,000 children every year, the majority of whom are under 5 years of age, have ear tubes inserted.

Some doctors are hopeful that the first guidelines on when to use ear tubes, issued last year by the American Academy of Otolaryngology—Head and Neck Surgery Foundation, will reduce unnecessary procedures and encourage more doctors and parents to go the

"watchful waiting" route.

While it's too early to tell, "anecdotally it does seem to have made a difference," said Richard Rosenfeld, chairman of otolaryngology at SUNY Downstate Medical Center in Brooklyn, N.Y. He chaired the task force that drew up the guidelines.

The guidelines state that for children with recurrent ear infections, ear tubes, or tympanostomy tubes, should be put in place only if middle-ear fluid is also present in at least one ear at the time of inspection. Children with persistent fluid buildup in the middle ear of both ears for at least three months, with or without an ear infection, are also candidates for ear-tube surgery.

Previously many doctors recommended ear tubes in children who either had recurrent ear infections—three in six months or four in a year—without fluid, or middle-ear effusion. Ear infections are concerning because of potential hearing loss that could cause developmental delays.

Contributing to a desire by doctors and parents to avoid surgery are concerns about the use of general anesthesia in young children. Researchers and doctors are exploring devices that would enable ear-tube procedures to be performed using alternatives. Preceptis Medical, a Plymouth, Minn., company, is testing a device, the Hummingbird, that uses nitrous oxide instead of general anesthesia in clinical trials at four sites, including the Mayo Clinic. Acclarent, a division of Johnson & Johnson^[1], JNJ -0.08%^[2] Johnson & Johnson^[3] U.S.: NYSE \$102.45 -0.08 -0.08% June 16, 2014 4:02 pm Volume (Delayed 15m) : 5.51M AFTER HOURS \$102.45 0.00% June 16, 2014 7:05 pm Volume (Delayed 15m): 133,069 P/E Ratio 19.19 Market Cap \$289.84 Billion Dividend Yield 2.73% Rev. per Employee \$561,148 06/16/14 Effort Seeks to Reduce Ear-Tub...^[4] 06/16/14 Showdown for Surgical Tool^[5] 06/15/14 Perennial Target Smith & Nephe...^[6] More quote details and news »^[7] JNJ^[8] Your Value Your Change Short position is working on using technologies that may allow for ear-tube procedures to be done in-office without general anesthesia, a spokeswoman said.

To insert tubes, doctors make a small cut in the eardrum and place the tiny, cylinder-like tube through it. It takes less than 10 minutes. The tube helps with air flow and prevents the buildup of fluids behind the eardrum. The tubes usually fall out within a year or two, and the holes close on their own, though sometimes a doctor must close them surgically. Children with tubes can still get ear infections, but doctors say they are

generally less frequent, milder and can be treated with antibiotic drops.

Tympanostomy tubes were among the five topics addressed at a 2012 national summit on overuse, said Lawrence Kleinman, vice chair for research and education in the department of health evidence and policy at Mount Sinai School of Medicine in New York. "Our conclusion was that there was overuse, but exactly how much was open to some discussion," said Dr. Kleinman, who sat on the advisory panel. His research suggests that more than one in five of the surgeries are unlikely to provide a meaningful benefit.

Emily Boss, a pediatric otolaryngologist at Johns Hopkins University School of Medicine, said she will find out how ear infections—either recurrent infections or chronic fluid in the ears—are affecting a family's daily life. Is a child going to the pediatrician every month? If the child meets the clinical criteria and the family is ready to take the next step, she said, ear tubes can be quite effective.

Doctors say parents frequently raise concerns about putting such young children under anesthesia. Ongoing studies on the effects of anesthesia on young children have shown there is some evidence of cognitive effects later in life, though the research isn't conclusive.

Randall Flick, director of the Mayo Clinic Children's Center, said his and other studies show the risk seems to occur after multiple exposures.

A study published last week, however, in the online version of the journal *Neuropsychopharmacology* found that children under 12 months old who received general anesthesia had problems with short-term memory later. Greg Stratmann, lead author of the study and a pediatric anesthesiologist in Los Gatos, Calif., said the study compared 28 children, ages 6 to 11, with a control group. The children who had anesthesia as infants performed 20% worse than the control group. Though most of the children had lengthy procedures, one had a surgery that lasted just 15 minutes. One surprising finding: researchers found no correlation between cumulative anesthetic dose and severity of the memory deficit.

Preceptis Medical is testing a device, called a hummingbird, which lets doctors make the incision in the ear drum and insert the tube at the same time. It uses nitrous oxide instead of general anesthesia. The company hopes the device, which would require clearance by the Food and Drug Administration, will be on the market next year, said

Steve Anderson, Preceptis chief executive.

Dr. Rosenfeld is one of a few doctors in the country who conducts ear-tube surgery without anesthesia. He offers it to children up to 18 months old and says about 20% of his patients select it. He swaddles the child on a board with Velcro straps.

Scott Kern had anesthesia-free surgery for his then 13-month-old son, Theo who had problems with both recurrent infections and persistent fluid. "We liked the idea of an eight-minute procedure that was done in the office, versus several hours in the hospital," said Mr. Kern, a 34-year-old Brooklyn teacher. He and his wife were also concerned about anesthesia.

Theo was strapped to a board to immobilize his head. The immobilization was what upset him, Mr. Kern said. "The procedure took maybe eight minutes or so and he stopped crying probably within 10 seconds."

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1. <http://quotes.wsj.com/JNJ>
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