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FDA considers parent preferences, children's experience in approving novel myringotomy, tube placement device

by from the Food and Drug Administration's Center for Devices and Radiologic Health, Office of Pediatric Therapeutics and Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health

The Food and Drug Administration (FDA) approved a novel device for myringotomy and tube placement in patients 6 months of age and older. The Tubes Under Local Anesthesia (Tula) System is the first myringotomy device approved for use by otolaryngologists in the outpatient setting without the need for general anesthesia.

In approving Tula, the Center for Devices and Radiological Health (CDRH) considered preferences of parents and caregivers as well as outcomes in pediatric patients.

"For the first time in FDA history, we are scientifically incorporating not only preference information in devices intended for adults but also for devices intended to help pediatric patients," said Vasum Peiris, M.D., M.P.H., FAAP, a pediatric and adult congenital cardiologist and CDRH's chief medical officer and director for pediatrics and special populations.

A study of 400 patients and caregivers indicated that the Tula in-office procedure was preferred over tube placement under general anesthesia in the operating room if Tula's success rate exceeded 68%.

An efficacy study of Tula in 222 pediatric patients demonstrated tube-placement success of 86% for patients younger than 5 years and 89% for patients 5-12 years. The most common adverse event was inadequate anesthesia.

Pediatric pain assessment tools were used to evaluate pain on a standard 10-point scale. During tube insertion, average pain scores of 4 and 3.3 were observed or reported for younger and older pediatric patients, respectively. Scores decreased to 1.3 and 1.7 at the end of the procedure.

The CDRH Program for Pediatrics and Special Populations in conjunction with the Patient Science and Engagement Program continues to advance the science of pediatric patient/caregiver preference assessment for regulatory decision-making. By promoting evaluation of the pediatric patient experience during clinical trials, novel technologies may mitigate peri-surgical and peri-interventional stressors.

Understanding the patient/caregiver perspective enhanced the FDA's assessment of Tula's benefits and risks.

"Children deserve to be heard, to have a voice in their care," Dr. Peiris said.

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