

Ototoxicity Not Seen With Brief Trial of Cortisporin

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LOS ANGELES — Cortisporin Otic did not cause ototoxicity and was cost effective when used for 5 days after ear tube placement surgery in children, according to a large retrospective review at a tertiary otologic center.

Newer fluoroquinolone agents are effective, but the cost is significant, Leonard P. Berenholz, M.D., reported at the annu-

al meeting of the American Academy of Otolaryngology–Head and Neck Surgery Foundation.

“The motivation for this study began after our entire group felt significant pressure to prescribe only fluoroquinolones, which perhaps many of you have felt as well,” he said.

Dr. Berenholz and his colleagues at the Lippy Ear Group in Warren, Ohio, found no evidence of clinical ototoxicity in 500 children who received Cortisporin

(neomycin, polymyxin B sulfates, and hydrocortisone otic solution) or a generic equivalent for 5 days after ventilation tube placement.

Audiometric testing after tube placement showed normal hearing in 872 (94.4%) of the 924 ears. A conductive hearing loss was found in 33 ears (3.6%).

A sensorineural hearing loss was present in 19 cases (2.1%). The loss existed prior to surgery in all 19 cases, and there was no deterioration postoperatively, he said.

An analysis showed the total cost for using Cortisporin or a generic was \$15,500 at \$31 a bottle. That compares with \$45,000 if Floxin (ofloxacin otic solution 0.3%) had been prescribed at \$90 per bottle, and \$49,500 if Ciprodex (ciprofloxacin 0.3% and dexamethasone 0.1% sterile otic suspension) had been prescribed at \$99 per bottle.

The investigators also contacted national trial lawyer associations and found no ototoxicity cases settled in or out of court, he said.

The makers of Ciprodex and Floxin see things differently.

“The FDA label for products containing aminoglycosides such as Cortisporin indicate the potential risk when there is an open tympanic membrane,” said Paul Cockrum, Pharm.D., manager of clinical

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market support for Alcon Inc., which manufactures Ciprodex. “So if a physician prescribes this product, then he is open to potential liability. Since Cortisporin offers no clinical benefits, any cost benefits are outweighed by

the risk of ototoxicity.”

He also noted that a consensus panel was formed in 2004 at the request of the American Academy of Otolaryngology–Head and Neck Surgery Foundation due to rising legal claims against physicians, recommendations by British and Canadian medical organizations to limit the use of potentially ototoxic otological antibiotics, the availability of nonototoxic preparations, and a lack of an evidence-based review of these issues.

The panel said, when possible, topical antibiotic preparations free of potential ototoxicity should be used. But the academy has elected not to convert the recommendations to official policy, said Kenneth Satterfield, media relations director for the academy.

The approved label for Cortisporin-TC Otic states that, “Neomycin can induce permanent sensorineural hearing loss due to cochlear damage, mainly destruction of hair cells in the organ of Corti” and that “ototoxicity and nephrotoxicity have also been reported,” commented Melvyn Bloom, M.D., director of medical services and safety for Daiichi Pharmaceutical Corp., which markets Floxin Otic.

Based on his findings, Dr. Berenholz recommends using Cortisporin for less than 1 week and reserving the tertiary character of fluoroquinolones for resistant or acute cases or difficult chronic ears.

“It would be a shame if 10 years from now we have problems with resistance to topical fluoroquinolones, although none have been reported,” he said.

A three-arm study is planned to evaluate children who had ear tubes placed without postoperative topical antibiotic drops and those who received Cortisporin or Ciprodex. ■

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