primary studies - published RCT

A randomized, controlled trial of a community-based support program for families of children with chronic illness: pediatric outcomes.

Code: PM12038883 **Year:** 2002 **Date:** 2006 **Author:** Chernoff RG

Study design (if review, criteria of inclusion for studies)

randomized controlled trial of once- versus three-times-daily tobramycin for pulmonary exacerbations of cystic fibrosis (the TOPIC study)

Participants

244 patients, of whom 219 (125 children and 94 adults) completed treatment. Nineteen patients were excluded from analysis due to abnormal baseline audiometry. Complete pre- and posttreatment standard audiological data were obtained for 168/219 patients

Interventions

standard pure tone audiometry performed across the frequency range of 0.25 to 8 kHz. High-frequency pure tone audiometry over 10 to 16 kHz was also performed with a subset of patients. Audiometry was undertaken at the start of tobramycin treatment, at the end of a 14-day course of treatment, and at follow-up 6 to 8 weeks later

Outcome measures

hearing thresholds

Main results

no significant differences in hearing thresholds when they were assessed at the baseline, at the end of treatment, and at follow-up 6 to 8 weeks later were compared. In addition, no significant differences in hearing thresholds were detected between treatment regimens. Similar results were obtained for the subset of 63/168 patients who underwent high-frequency audiometry.

Authors' conclusions

for a single 14-day course of tobramycin treatment in patients with cystic fibrosis with no preexisiting auditory deficit, no measurable effect on hearing was apparent with either once- or three-times-daily treatment. Estimation of the cumulative cochleotoxic risk in cystic fibrosis patients due to repeated aminoglycoside therapy, as evidenced by the patients excluded from this study due to hearing loss, also requires further characterization.

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See also

Arch Pediatr Adolesc Med. 2002 Jun;156(6):533-9.

Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Child; Drug Administration Schedule; Infection; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;