primary studies - published RCT

Intermittent administration of inhaled tobramycin in patients with cystic fibrosis. Cystic Fibrosis Inhaled Tobramycin Study Group.

Code: PM9878641 **Year:** 1999 **Date:** 2002 **Author:** Ramsey BW

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

randomized, double-blind, cross-over study

Participants

Of 19 children with CF (age range, 7 to 16 years) with mild-to-moderate pulmonary disease, 10 children were at high risk (HR) for bronchospasm (family history of asthma and previous response to bronchodilators) and 9 children were at low risk (LR) for bronchospasm (no family history of asthma or previous response to bronchodilators).

Interventions

Two solutions of tobramycin were administered: (1) 80 mg in a 2-mL vial diluted with 2 mL of saline solution containing the preservatives phenol and bisulfites (IV preparation); and (2) 300 mg in a preservative-free preparation in a 5-mL solution. Following a bronchodilator-free period of 12 h, the patients inhaled either one or the other preparation in random order on two different occasions, 2 weeks apart

Outcome measures

FEV1

Main results

Prechallenge and postchallenge results for the LR group showed a percentage of fall in FEV(1) (DeltaFEV(1)) of 12 +/- 9% (mean +/- SD) for the IV preparation, compared to 4 +/- 5% for the preservative-free preparation (p = 0.046). An DeltaFEV(1) of > 10% was seen in six of nine patients for the IV preparation and in one of nine patients for preservative-free preparation. For the HR group, the DeltaFEV(1) was 17 +/- 13% for the IV-preparation group, compared to 16 +/- 12% for the preservative-free group (p = 0.4). In this group, equal numbers of patients (8 of 10 patients) had an DeltaFEV(1) > 10% after inhaling each preparation. The largest DeltaFEV(1) was 44% (HR group with the preservative-free preparation that forced the early termination of inhalation).

Authors' conclusions

Both preparations caused significant bronchoconstriction in the HR group, and the preservative-containing IV preparation caused more bronchospasm in LR group than the preservative-free solution. Heightened airway reactivity in children with CF places them at risk of bronchospasm from inhalation therapy.

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See also

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Keywords

Adolescent; Anti-Bacterial Agents; Bacterial Infections; Child; Infection; Inhalation OR nebulised; pharmacological_intervention; Pneumonia; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Tobramycin; Aminoglycosides;