primary studies - published RCT

The efficacy and safety of meropenem and tobramycin vs ceftazidime and tobramycin in the treatment of acute pulmonary exacerbations in patients with cystic fibrosis.

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

blinded RCT.

Participants

Patients who were > or = 5 years of age who were infected with ceftazidime-susceptible Pseudomonas aeruginosa were stratified by lung function and randomized to treatment with meropenem/tobramycin or ceftazidime/tobramycin. Patients infected with Burkholderia cepacia complex or ceftazidime-resistant P aeruginosa were assigned to receive open-label meropenem/tobramycin. 102 CF patients

Interventions

IV meropenem (40 mg/kg to 2 g q8h) or ceftazidime (5 mg/kg to 2 g q8h), each of which was administered with IV tobramycin (at a serum peak of > or = 8 microg/mL and a trough of

Outcome measures

Clinical response was assessed by spirometry to determine the change in percent predicted FEV1 and by a clinical acute change score (ACS)

Main results

patients were randomized to meropenem/tobramycin (n = 50) or ceftazidime/tobramycin (n = 52). Nineteen patients received open-label meropenem/tobramycin. FEV1 was improved at the end of treatment (EOT) with meropenem/tobramycin (mean [+/- SD] increase, 38.8 +/- 52.3%) and with ceftazidime/tobramycin (mean increase, 29.4 +/- 35.1%; p < 0.0001 vs baseline values). The proportion of patients with > or = 15% relative increase from baseline FEV1 (satisfactory response) at day 7 was 62% for the meropenem/tobramycin group and 44% for the ceftazidime/tobramycin group (p = 0.04). The median time to FEV1 response was 4 days for meropenem/tobramycin therapy vs 6 days for ceftazidime/tobramycin therapy. Similarly, FEV1 improved in the open-label group (mean increase, 12.5 +/- 25.7%; p = 0.05). ACS improved in all three groups at EOT (p

Authors' conclusions

Therapy with both meropenem/tobramycin and ceftazidime/tobramycin improved pulmonary and clinical status and reduced sputum bacterial burden in CF patients with APEs. A larger proportion of patients receiving meropenem/tobramycin therapy demonstrated a satisfactory FEV1 response at day 7. Resistant P aeruginosa emerged infrequently during treatment with both regimens.

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See also

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Keywords

Adolescent; Adult; Anti-Bacterial Agents; Bacterial Infections; Burkholderia cepacia; Ceftazidime; Child; Combined Modality Therapy; Infection; Meropenem; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Thienamycin; Tobramycin; Exacerbation; Cephalosporins; Carbapenems; Aminoglycosides;