primary studies - published RCT

Intravenous colistin sulphomethate in acute respiratory exacerbations in adult patients with cystic fibrosis.

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

RCT

Participants

53 CF patients, 18 of whom entered the study twice, were enrolled. Patients with chronic Pseudomonas aeruginosa colonisation who presented with protocol defined respiratory tract exacerbations

Interventions

12 days with either colistin (2 MU tds intravenously) alone or with a second anti-pseudomonal antibiotic.

Outcome measures

Comparisons of the absolute values of respiratory function tests on days 1, 5, and 12 and of overnight oxygen saturation on days 1 and 12 were the primary outcome measures. Patient's weight, clinical and chest radiographic scores, and peripheral blood markers of inflammation were also documented. The effect of each treatment regimen individually was assessed by the change in clinical measurements from baseline values. Adverse renal effects were monitored by measurement of serum levels of urea and electrolytes, creatinine clearance, and ward urine testing. Neurotoxicity was monitored by direct questioning for symptoms.

Main results

The mean forced expiratory volume in one second (FEV1) increased significantly in both groups, mean forced vital capacity (FVC) only with dual therapy. Both groups showed a non-significant increase in overnight oxygen saturation. All patients showed clinical improvement. Thirty seven adverse neurological events (two severe) were reported in 33 patients in the monotherapy group and 37 (none severe) in 36 patients in the dual therapy group. One patient withdrew because of severe weakness and dizziness. All other adverse neurological events were well tolerated and resolved during or shortly after treatment. Significant changes were seen in mean serum urea levels in both groups, but in only four patients to a level above the normal range, and in creatinine clearance in the dual therapy group. At 24 month follow up no long term adverse consequences from intravenous colistin were found in patients who completed the study.

Authors' conclusions

Intravenous colistin is an effective treatment for Pseudomonas aeruginosa associated pulmonary exacerbations in patients with cystic fibrosis. Assessment of the individual effect of each treatment regimen suggests a greater efficacy when colistin is combined with a second antibiotic to which the pseudomonas shows in vitro sensitivity. Changes in renal function should be monitored.

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See also

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Keywords

Adult; Anti-Bacterial Agents; Bacterial Infections; Colistin; Combined Modality Therapy; Drug Administration Schedule; Infection; Intravenous; pharmacological_intervention; Pseudomonas aeruginosa; Pseudomonas; Respiratory Tract Diseases; Respiratory Tract Infections; Exacerbation; other anti-bacterial agents;