primary studies - published RCT

Mucus clearance and lung function in cystic fibrosis with hypertonic saline.

Code: PM16421365 **Year:** 2006 **Date:** 2006 **Author:** Donaldson SH

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

randomized trial

Participants

24 CF patients

Interventions

inhaled hypertonic saline (5 ml of 7 percent sodium chloride) four times daily with or without pretreatment with amiloride

Outcome measures

Mucus clearance and lung function were measured during 14-day baseline and treatment periods

Main results

Long-term inhalation of hypertonic saline without pretreatment with amiloride (i.e., with placebo pretreatment) resulted in a sustained (> or =8 hours) increase in 1-hour rates of mucus clearance, as compared with those with amiloride pretreatment (14.0+/-2.0 vs. 7.0+/-1.5 percent, respectively; P=0.02) and increased 24-hour rates of mucus clearance over baseline. Furthermore, inhalation of hypertonic saline with placebo improved the forced expiratory volume in one second (FEV1) between the baseline period and the treatment period (mean difference, 6.62 percent; 95 percent confidence interval, 1.6 to 11.7; P=0.02), whereas hypertonic saline with amiloride did not improve FEV1 (mean difference, 2.9 percent; 95 percent confidence interval, -2.2 to 8.0; P=0.23). Forced vital capacity (FVC), the forced expiratory flow between 25 and 75 percent of FVC (FEF25-75), and respiratory symptoms also significantly improved in patients treated with hypertonic saline and placebo, whereas the residual volume as a proportion of total lung capacity (RV:TLC) did not change in either group. A comparison of the changes in lung function in the two groups showed no significant difference. In vitro data suggested that sustained hydration of airway surfaces was responsible for the sustained improvement in mucus clearance, whereas inhibition of osmotically driven water transport by amiloride accounted for the observed loss of clinical benefit.

Authors' conclusions

In patients with cystic fibrosis, inhalation of hypertonic saline produced a sustained acceleration of mucus clearance and improved lung function. This treatment may protect the lung from insults that reduce mucus clearance and produce lung disease.

http://dx.doi.org/10.1056/NEJMoa043891

See also

N Engl J Med. 2006 Jan 19;354(3):241-50.

Keywords

Adolescent; Adult; Amiloride; hydration; Hypertonic Solutions; Inhalation OR nebulised; pharmacological_intervention; ENaC antagonists - Sodium Channel Blockers; Water; Airway clearance drugs -expectorants- mucolytic- mucociliary-; Sodium Chloride; Respiratory System Agents;