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Cystic Fibrosis Research News

Title:

Safety and Efficacy of Prolonged Levofloxacin Inhalation Solution (1 APT-1026) Treatment for Cystic Fibrosis and Chronic *Pseudomonas aeruginosa* Airway Infection

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What was your research question?

Previously, we have shown that a new inhaled form of an antibiotic commonly used in cystic fibrosis (CF) care, levofloxacin, improves lung function and decreases the likelihood of a pulmonary exacerbation (a flare up of symptoms) in patients with CF. Our prior study found that inhaled levofloxacin worked as well as inhaled tobramycin. We wanted to see if the effectiveness and safety of inhaled levofloxacin persisted with longer-term use.

Why is this important?

Many people with cystic fibrosis have long-term infection of their lungs, most commonly with the bacterium *Pseudomonas aeruginosa*. Long-term *P. aeruginosa* infection is usually treated with inhaled antibiotics to suppress the infection, reduce the risk of pulmonary exacerbations, improve a person's quality of life, and preserve lung function. Although several inhaled antibiotics are available, alternative options are needed, because the antibiotics may become less effective or patients may not be able to tolerate them.

What did you do?

In a previous study, we compared the new antibiotic, levofloxacin inhalation solution, with inhaled tobramycin, which is currently used for *P. aeruginosa* lung infection. Both

treatments were given twice daily for 28 days followed by 28 days without inhaled antibiotic treatment for 3 on-treatment/off-treatment cycles (total of 6 months). At the end of this study, patients who had received either treatment were offered the option of treatment for an additional 3 cycles of 28 days with levofloxacin and 28 days of observation. We measured lung function, quality of life, and the time to a pulmonary exacerbation in the 88 participants, who completed the extended study.

What did you find?

Extended treatment with levofloxacin inhalation solution showed a sustained benefit on lung function and quality of life. Similar to the initial study, the medication was generally well-tolerated with the main complaint from some patients being an unpleasant taste of the medication.

What does this mean and reasons for caution?

This means that the new inhaled antibiotic may have a role in the treatment of patients with CF who have *P. aeruginosa* infection of the airways. Inhaled levofloxacin may be an alternative to currently available antibiotics.

What's next?

The drug has been approved in some countries, so now we can assess the long-term safety and benefits in patients who are treated with it.

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