Cystic Fibrosis Research News

Title:

Changes in symptom scores as a potential clinical endpoint for studies of cystic fibrosis pulmonary exacerbation treatment

Authors:

VanDevanter DR[1], Heltshe SL[2,3], Sanders DB[4], West NE[5], Skalland M[2], Flume PA[6], Goss CH[2,3,7], on behalf of the STOP-OB Study

Affiliations:

[1]Department of Pediatrics, Case Western Reserve University School of Medicine, Cleveland, OH.
[2]CFF Therapeutics Development Network Coordinating Center, Seattle Children's Research Institute, Seattle, WA.
[3]Departments of Pediatrics, University of Washington, Seattle, WA.
[4]Department of Pediatrics, Indiana University School of Medicine, Indianapolis, IN.
[5]Department of Medicine, Johns Hopkins University, Baltimore, MD.
[6]Departments of Medicine and Pediatrics, Medical University of South Carolina, Charleston, SC.
[7]Department of Medicine, University of Washington, Seattle, WA

What was your research question?

The Chronic Respiratory Infection Symptom Score (CRISS), which ranges from 0 to 100, comes from an 8-question survey given to people with CF having a flare up of lung infection (pulmonary exacerbation). We wanted to understand how the CRISS could be used in clinical trials to tell how well drugs to treat exacerbations are working.

Why is this important?

It has been shown that people with CF who are having an exacerbation are most concerned with having their symptoms (for example, cough or trouble breathing) go away with treatment, while their doctors are more interested in recovering lost lung function. Today, therapies to treat exacerbations are tested based on how they improve lung function, not on how they improve exacerbation symptoms. Because the CRISS score can show how exacerbation symptoms change with treatment, and because information comes from the person being treated, it may be a useful tool for studying how well exacerbation treatments work.

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What did you do?

We studied CRISS scores collected each day from people with CF who participated in a study of intravenous (IV) antibiotic treatments for pulmonary exacerbations. We looked at how long after start of treatment it took CRISS scores to drop by 11 points (because lower CRISS is better and because 11 points is the smallest change that is clinically meaningful). We also studied how long it took for people in the study to reach the greatest average CRISS drop seen in the study, 26 points, and how age, lung function, and starting CRISS score affected how CRISS changed with treatment.

What did you find?

CRISS scores from 173 people with CF treated for exacerbations were studied. Half of these people had their CRISS scores drop 11 points in only two days of antibiotic treatment and half had a CRISS drop of 26 points by 17 days of antibiotic treatment. People who entered the study with higher (worse) CRISS scores and those who were younger had a greater chance of having a 26-point drop within 14 days of starting treatment than those with either lower CRISS scores or who were older when treatment started.

What does this mean and reasons for caution?

The CRISS score performed well measuring the effects of antibiotic treatment (treatment response). Changes in CRISS were relatively large and occurred rapidly, which make it easier to measure treatment response. Big differences in CRISS changes during antibiotic treatment were not seen for people with different levels of lung damage or of different ages, which means that the CRISS can measure response in a wide variety of people with CF. Not all people in the study were able to complete the 8-question CRISS survey frequently enough to be included in this study, so less frequent CRISS measurement may work better in future trials.

What's next?

Our results suggest that the CRISS should be used in clinical trials as a measure of how people with CF respond to pulmonary exacerbation treatments. A drug developer is currently planning to use the CRISS to study response to a new antibiotic to treat CF pulmonary exacerbations.

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cfresearchnews@gmail.com