

Cystic Fibrosis Research News

Title:

PANCREATIC ELASTASE-1 QUICK TEST FOR RAPID ASSESSMENT OF PANCREATIC STATUS IN CYSTIC FIBROSIS PATIENTS.

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What was your research question?

This prospective study evaluates the accuracy of the new test - Pancreas Elastase-1 Quick™ Test - in terms of sensitivity (how well the test correctly identifies those with the disease) and specificity (how well the test identifies those who definitely do not have the disease). We did this by comparing the results with the ELISA test, the gold standard for non-invasive pancreatic function assessment.

Why is this important?

Pancreatic insufficiency causes malnutrition and poor clinical status, so it is crucial to rapidly and accurately determine pancreatic status in people with cystic fibrosis (CF). Direct tests (such as the gold standard secretin-cholecystokinin test) are time consuming, invasive, and expensive for routine evaluation; but the choice of the test should be based on its sensitivity, specificity and convenience. Pancreas Elastase-1 Quick™ Test aims for a rapid diagnosis of pancreatic insufficiency in people with CF, because the results of the test are available within 5 minutes after a stool (poo) sample has been taken.

What did you do?

We used two diagnostic tests Pancreas Elastase-1 Quick™ Test (ScheBo® Biotech AC, Giessen, Germany) and fecal elastase-1 ELISA kit (ScheBo® Biotech AC, Giessen, Germany) – to evaluate each person's pancreatic status. The fecal elastase-1 test was used as the reference test (i.e. the most accurate test currently available to compare the new test to). In



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order to assess the sensitivity and specificity of the Elastase-1 Quick™, we obtained stool samples from 28 children with CF diagnosed in a CF screening program, 36 children in whom CF was excluded in the course of a CF screening program and 62 people diagnosed with CF in a classical way (total of 126 participants).

What did you find?

The study shows that the Pancreatic Elastase-1 Quick™ Test has high sensitivity (test correctly identified 92.8% of people with pancreatic insufficiency) and specificity (test correctly identified 96.6% of people who were not pancreatic insufficient).

What does this mean and reasons for caution?

Elastase-1 ELISA stool test has been shown to be the most reliable indirect test for the assessment of pancreatic function. However, in many CF centers the samples are analyzed for fecal elastase-1 once per year or even less frequently and results are not available straight away. We are convinced that especially for babies with CF, this is not sufficient and we should have an immediate answer. The Pancreas Elastase-1 Quick Test™ is cheap, easy to perform and is a reliable test. In a clinical setting it is a reasonable measure allowing for the immediate assessment of pancreatic status.

What's next?

Pancreatic Elastase-1 Quick Test™ is a rapid and reliable option for evaluating pancreatic function, that could be potentially used in neonatal screening programs as well as for the long-term follow up of individuals who are pancreatic sufficient.

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