

Use of fecal Elastase-1 to classify pancreatic Status in Patients with Cystic Fibrosis

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OBJECTIVE: To test the hypothesis that some patients with cystic fibrosis (CF) are misclassified as pancreatic insufficient, using fecal elastase-1 (FE-1) to define pancreatic status. **Study design** Subjects with CF at 33 CF centers filled out questionnaires and submitted a stool specimen that was analyzed for FE-1. Subjects taking pancreatic enzyme supplements (PES) were asked to discontinue them and perform a 3-day fecal fat balance study if their FE-1 was >200 microg/g stool and they had never had pancreatitis. **RESULTS:** The median value for FE-1 in 1215 subjects was 0 microg/g stool (range, 0-867). There was a significant difference between patients who had been prescribed PES (n=1131) and those who had FE-1 <200 microg/g stool (n=1074; P<.0001). Sixty-seven subjects met criteria for discontinuation of PES. The mean coefficient of fat absorption for these subjects was 96.1%. **CONCLUSIONS:** FE-1 is an accurate, easily obtained screening test to classify pancreatic status in patients with CF. This information is important for prognostication, treatment, and to avoid misclassification in clinical research. Measurement of FE-1 should become a standard of care for patients with CF.