primary studies - published, non RCT

High-dose pancreatic-enzyme supplements and fibrosing colonopathy in children with cystic fibrosis.

Code: PM9113931 **Year:** 1997 **Date:** 1997 **Author:** FitzSimmons SC

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

retrospective, case-control study

Participants

Children with histopathologically confirmed cases of fibrosing colonopathy who required colectomy for colonic strictures from January 1, 1990, through December 31, 1994, were identified. Each of these patients was matched according to age at the time of surgery and medical center with up to four controls with cystic fibrosis who did not have fibrosing colonopathy.

Interventions

pancreatic-enzyme supplement

Outcome measures

Fibrosing colonopathy

Main results

We studied 29 patients (mean age, 5.0 years) with fibrosing colonopathy (case patients) and 105 controls (mean age, 5.2 years). The mean dose of pancreatic-enzyme supplement was 50,046 units of lipase per kilogram of body weight per day for the case patients and 18,985 units per kilogram per day for the controls. A history of gastrointestinal complications attributed to cystic fibrosis and the use of histamine H2-receptor blockers, corticosteroids, or recombinant human DNase (dornase alfa) were associated with a higher incidence of fibrosing colonopathy. After adjustment for a history of such complications and the use of these medicines, the relative risk of fibrosing colonopathy that was associated with a dose of 24,001 to 50,000 units of lipase per kilogram per day, as compared with a dose of 0 to 24,000 units per kilogram per day, was 10.9 (95 percent confidence interval, 1.6 to 71.8), and that associated with a dose of more than 50,000 units per kilogram per day was 199.5 (95 percent confidence interval, 9.9 to 4026.0). The strength, coating, and manufacturer of the products used were not associated with the risk of fibrosing colonopathy.

Authors' conclusions

In young children with cystic fibrosis, we found a strong relation between high daily doses of pancreatic-enzyme supplements and the development of fibrosing colonopathy. Our findings support recommendations that the daily dose of pancreatic enzymes for most patients should remain below 10,000 units of lipase per kilogram.

http://dx.doi.org/10.1056/NEJM199705013361803

See also

N Engl J Med. 1997 May 1;336(18):1283-9.

Keywords

Child; Gastrointestinal Agents; Infant; pharmacological_intervention; Pancreatic Enzyme Replacement Therapy; Supplementation; Pancreas insufficiency; Pancreatic Diseases; Gastrointestinal Diseases; Malabsorption; Nutrition Disorders; Fibrosing colonopathy; Creon; ULTRASE;