

Acid reflux without symptoms does not worsen asthma

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A commonly used treatment for acid reflux does not improve asthma symptoms or control in patients who do not have symptoms of gastroesophageal reflux (GER), according to a new study supported by the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health and by the American Lung Association (ALA). This suggests that silent GER (acid reflux that causes only minimal or no reflux symptoms) does not play a role in asthma, as has previously been thought.

The multi-center, randomized clinical trial is the first to evaluate whether adding esomeprazole (Nexium), to <u>asthma</u> therapy might improve asthma control and quality of life in asthma patients who could have silent GER. Esomeprazole is a type of medication called a proton pump inhibitor (PPI), which is used to treat heartburn, GER, and ulcers by reducing stomach acid. Researchers found no differences between patients treated with the reflux medication and those who were not. The results are published in the April 9, 2009, issue of the <u>New England</u> <u>Journal of Medicine</u>.

"This study helps us rule out silent GER as one possible contributor to poorly controlled asthma, and is important news for many patients," said NHLBI Director Elizabeth G. Nabel, M.D. "Asthma patients who take medication for <u>acid reflux</u> but who do not have reflux symptoms should talk with their doctors about whether they should continue the medication."



Asthma is a common and complex condition that affects more than 22 million Americans. Between 32 percent and 84 percent of people who have asthma also have GER, with nearly half of them having no or minimal reflux symptoms. During GER, food or fluid rises from the stomach into the esophagus (the tube that carries substances from the mouth to the stomach) because the muscles linking the esophagus to the stomach fail to close properly or they open spontaneously. Because GER is more common in asthma patients than in the general population, it has been commonly believed that acid reflux might contribute to worsening of asthma symptoms such as coughing, wheezing, and shortness of breath, in part because GER might cause the airways to narrow. The relationship between asthma and GER is complex and not well understood, however. Nonetheless, medication for acid reflux is often prescribed to patients whose asthma is poorly controlled, even when reflux symptoms are lacking.

The new study followed 402 adults (average age 42) with poorly controlled asthma despite taking moderate or higher doses of inhaled corticosteroids. Participants reported that they did not have GER symptoms or that they had a history of GER but their symptoms were minimal and they were not taking anti-reflux medication. Researchers tested for GER with a probe to measure acidity (pH) levels in the esophagus and found that about 40 percent of participants had silent GER.

Participants were randomly selected to either use esomeprazole (40 milligrams) twice daily or a similar looking placebo (inactive ingredient) for six months while continuing to take their asthma medications. They tracked their symptoms and asthma control through asthma diaries, and visited the research clinic monthly for lung function testing. They also completed standard quality-of-life questionnaires.

Overall, the numbers and severity of asthma symptoms, and quality-of-



life scores were similar between participants taking esomeprazole and participants who did not take the anti-reflux medication. In addition, the outcomes were similar among subgroups of participants, such as those with silent GER, those who were overweight or obese, and those who had frequent night awakenings due to asthma.

"This study demonstrates that silent GER does not play a role in worsening asthma symptoms and control," said Robert A. Wise, M.D., a coauthor of the paper and a professor at Johns Hopkins University School of Medicine, where he is also director of the coordinating center for the ALA Asthma Clinical Research Centers. "Based on these results, we also believe that doctors do not need to test for GER in asthma patients unless the patient is reporting symptoms of acid reflux."

Asthma patients with GER symptoms, however, may find relief from acid reflux with esomeprazole or other PPIs.

The current asthma guidelines (Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma - Full Report, 2007) recommend anti-reflux treatment for patients who have reflux symptoms and a diagnosis of GER. The guidelines also suggest that physicians consider testing for GER in patients whose asthma is poorly controlled - especially those who have nighttime asthma symptoms - and treating silent GER. The recommendations on treating silent GER in asthma patients were based on extrapolating findings from studies on patients who have GER symptoms, however, because evidence from randomized controlled clinical trials in patients without GER symptoms was not available.

"This study fills a gap in our knowledge about the use of anti-reflux therapy in patients with poorly controlled asthma and it will help inform the next update of the asthma clinical guidelines," noted Virginia Taggart, M.P.H., program director in the NHLBI Division of Lung



Diseases, and the study's project officer.

The guidelines are developed by the National Asthma Education and Prevention Program (NAEPP), which is coordinated by NHLBI. NAEPP periodically convenes an expert panel to conduct a systematic review of the published medical literature to ensure that the asthma guidelines reflect the latest scientific advances.

The clinical trial was conducted at 19 sites: Baylor College of Medicine, Houston; Columbia University-New York University Consortium, New York City; Duke University Medical Center, Durham, N.C.; Emory University School of Medicine, Atlanta; Illinois Consortium, Chicago; Indiana University, Asthma Clinical Research Center, Indianapolis; Louisiana State University Health Sciences Center, Ernest N. Morial Asthma, Allergy, and Respiratory Disease Center, New Orleans; National Jewish Medical and Research Center, Denver; Nemours Children's Clinic-University of Florida Consortium, Jacksonville, Fla.; North Shore-Long Island Jewish Health System, New Hyde Park, N.Y.; The Ohio State University Medical Center/Columbus Children's Hospital, Columbus, Ohio; St. Louis Asthma Clinical Research Center: Washington University, St. Louis; University of Alabama at Birmingham; University of California San Diego; University of Miami, Miami-University of South Florida, Tampa; University of Minnesota, Minneapolis; University of Missouri, Kansas City School of Medicine; University of Pennsylvania, Philadelphia; University of Vermont, Burlington.

Esomeprazole and placebo used in the study was provided by its manufacturer, AstraZeneca, based in Wilmington, Del.

More information:

Asthma, www.nhlbi.nih.gov/health/dci/D ... a/Asthma WhatIs.html



Guidelines for the Diagnosis and Management of Asthma (EPR-3), <u>www.nhlbi.nih.gov/guidelines/asthma/index.htm</u> ALA Asthma Clinical Research Centers, <u>www.lungusa.org/site/pp.asp?c=dvLUK9O0E&b=37101</u> Gastroesophageal reflux, <u>digestive.niddk.nih.gov/ddiseases/pubs/gerd/</u>

Source: NIH/National Heart, Lung and Blood Institute

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