

Large placebo-controlled trial confirms safety of proton pump inhibitors (PPIs)

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For patients taking proton pump inhibitors (PPIs) to treat gastroesophageal disease (GERD) or other acid-related conditions, new research puts safety concerns to rest. In a large, multi-year, randomized trial studying the safety of proton pump inhibitors (PPIs), researchers find no evidence to support claims that PPIs cause serious health issues such as pneumonia, chronic kidney disease, diabetes and dementia. This research is published in *Gastroenterology*, the official journal of the American Gastroenterological Association, as an article in press.

PPIs are one of the most widely used classes of drugs in the U.S. PPIs are the most effective drugs for treating GERD, which occurs in over 25 percent of the population, and are recommended in many other acid-related conditions. As with all drugs, PPI therapy should only be used when the benefits are expected to outweigh the risks and should be used according to recommended dose and duration of treatment. However, this new research suggests that limiting prescriptions of PPI therapy because of concerns of long-term harm is not appropriate.

"Our research provides welcomed news for the countless patients who rely on PPIs to control their symptoms, as well as the physicians who prescribe this medication," said lead study author Paul Moayyedi, MB, ChB, Ph.D., The Population Health Research Institute, McMaster University and Hamilton Health Sciences, Hamilton, Ontario, Canada. "To our knowledge, this is the first prospective randomized trial to evaluate the many long-term safety concerns related to PPI therapy. It is reassuring that there was no evidence for harm for most of these events."

The trial included 17,598 patients assigned to groups given the PPI pantoprazole or placebo. The researchers collected data on development

of pneumonia, Clostridium difficile infection, other enteric infections, fractures, gastric atrophy, [chronic kidney disease](#), diabetes, chronic obstructive lung disease, dementia, cardiovascular disease, cancer, hospitalizations, and all-cause mortality every six months. The results show that pantoprazole is not associated with any adverse event when used for 3 years, with the possible exception of an increased risk of enteric infections. However, this risk is lower than estimated by previous systematic reviews of observational studies and should be interpreted with caution.

Tips for patients taking PPIs

1. Talk to your doctor before making any changes to your medication. You have been prescribed PPIs for a reason, to treat a diagnosed medical condition. You and your doctor can discuss the reason for your prescription, the dose and the timeframe for treatment.
2. Consider life-style modifications that may reduce or eliminate the need for PPIs for [long-term use](#). These may include weight loss, avoiding tobacco or a change in your eating patterns. Your doctor can help you determine the changes that are right for you.
3. Keep in touch with your doctor. Research continues to be done on PPI use. While headlines on PPIs may seem scary, this research reaffirms that patients who have a diagnosed condition that is helped by PPIs should stay on them, as benefits can outweigh risks.

More information: Paul Moayyedi et al, Safety of Proton Pump Inhibitors Based on a Large, Multi-year, Randomized Trial of Patients Receiving Rivaroxaban or Aspirin, *Gastroenterology* (2019). [DOI: 10.1053/j.gastro.2019.05.056](#)

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