

# Study questions association between common heartburn drugs and risk of pneumonia

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Previous studies that have associated the use of proton pump inhibitors (PPI) – which include popular anti-heartburn medications like Prilosec and Nexium – with an increased incidence of pneumonia may not have found a true cause-and-effect relationship. A study that has been released online by the *Journal of General Internal Medicine* outlines a strategy for determining when the results of such observational studies may have been distorted by unmeasured factors and then finds that may be the case with the association between PPIs and pneumonia risk.

"Our study is the first to show that use of PPIs most likely does not lead to higher rates of [pneumonia](#) or other [health problems](#) identified in observational studies," says Anupam Jena, MD, PhD, of the Massachusetts General Hospital ([MGH](#)) Department of Medicine, corresponding author of the article. "In fact, the associations observed in prior studies appear to reflect patient or [health provider](#) characteristics – such as patients' overall health and likelihood to seek [health care services](#) – not adequately accounted for in those studies. Understanding whether PPI use causes higher rates of other health problems is important, given the pervasive use of these medications."

Although observational studies – which examine whether factors ranging from personal behavior to the use of particular medications occur more frequently in people with certain health problems – can identify possible connections, they cannot prove that the examined factor actually caused the health problem. In the case of studies finding that patients taking PPIs were more likely to be diagnosed with pneumonia, the fact that

there was a plausible mechanism for the association – reduced production of [stomach acid](#) could allow increased growth of ingested bacteria – has led that finding to be widely accepted. Jena notes that many physicians have urged a reduction in PPI prescriptions and the FDA has issued warnings based on associations between PPIs and infectious diarrhea found in other observational studies.

To test the validity of the association between PPI use and the risk of pneumonia, Jena and his colleagues used a strategy called 'falsification,' which other researchers have suggested as a way to test observational associations. Analyzing data reflecting 11 years of insurance claims from almost 54,500 adult beneficiaries of six employer-based health plans, they compared PPI users with non-users in terms of whether they also had received diagnosis or treatment for several health problems – including osteoarthritis, chest pain, urinary tract infections and skin infections – for which no plausible mechanism could explain an increased risk caused by PPIs.

The results showed that patients taking PPIs were more likely than nonusers to have osteoarthritis, chest pain, urinary tract infections – along with pneumonia – and also to have been diagnosed or treated for health problems such as cancer, diabetes and stroke. Even during time periods when they did not have PPI prescriptions filled, [PPI](#) users had a greater likelihood of having those or other health problems that could not plausibly be caused by taking those drugs.

"Several unmeasured factors, including physicians' likelihood of diagnosing a condition or prescribing any medication, can confound associations like the one between PPIs and pneumonia," explains Jena, who is also an assistant professor of Health Care Policy at Harvard Medical School. "The classic example of the limitations of observational studies was the association between hormone replacement therapy and reduced heart disease in postmenopausal women, which was disproved

by randomized, controlled studies. Falsification testing can help assess whether the associations found in observational studies are real, and I think we should consider whether they should be required to validate all [observational studies](#)."

Provided by Massachusetts General Hospital

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