

Aspirin, acid blocker a-day keeps GI bleeding

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For patients with clogged heart arteries who take long-term, low-dose aspirin to prevent a cardiac event, adding a stomach acid-blocking drug to their daily routine has been shown to reduce their risk for upper gastrointestinal bleeding – an infrequent, but serious side-effect of regular aspirin use.

But do the benefits of these acid blockers – called proton pump inhibitors, or PPIs – outweigh their long-term costs?

In a new study, researchers at the University of Michigan Health System reveal that, from the perspective of a long-term payer, over-the-counter PPIs are worth the price for coronary heart disease patients taking low-dose aspirin as a preventative measure. At prescription costs, however, PPIs are cost-effective only for elderly patients and patients at high risk for upper GI bleeding.

"Our study was also able to demonstrate that, for patients at an average risk for GI bleeding, starting PPI cotherapy at a younger age was marginally cost-effective, while starting PPI cotherapy at an older age was highly cost effective," says Sameer Dev Saini, M.D., M.S., clinical lecturer in the Division of Gastroenterology at the U-M Medical School. "Ultimately, physicians should discuss the gastrointestinal risks of low-dose aspirin with their patients and consider PPI cotherapy."

Study results appear in the Aug. 11/25 issue of *Archives of Internal Medicine*.

Coronary heart disease is caused by gradual blockage of the heart arteries, which slows the flow of oxygen and blood to the heart.

Because clogged heart arteries put patients at an increased risk for heart attack and sudden death, medical guidelines recommend that they use low-dose aspirin daily to prevent future cardiovascular events.

Regular use of aspirin, however, poses a small risk for upper gastrointestinal bleeding.

"The stomach normally has a protective coating to prevent acid-related injury. But aspirin and other non-steroidal anti-inflammatory drugs, or NSAIDs, impair the stomach's ability to form this barrier coating, potentially leading to ulcer formation," explains Saini. "Furthermore, these drugs may themselves cause injury directly to stomach cells, and can impair the ability of platelets to form a plug in the event of bleeding."

While not regularly prescribed to coronary heart disease patients who take aspirin, Saini says PPIs taken on a daily basis can reduce a patient's risk for upper GI bleeding. In fact, U-M researchers were among the first to reveal that aspirin-related damage could be reduced by a PPI.

"Many Americans are currently taking low-dose aspirin for coronary heart disease, and we know that PPIs are effective in reducing ulcer bleeding in patients on aspirin," says Saini. "What we didn't know, however, was whether it is worth paying for these drugs for patients on low-dose aspirin who had no other risk factors."

With the recent availability of a low-cost OTC PPI – Prilosec OTC® – Saini and his colleagues wanted to explore its cost-effectiveness compared to higher-cost prescription PPIs. They also looked at the bigger picture: Is life-long PPI cotherapy cost-effective for patients

taking aspirin?

The study revealed:

- At OTC prices, PPI cotherapy is cost-effective for patients older than 65 who are taking low-dose aspirin, and may also be cost-effective for patients as young as 50.
- Even for patients who have an average risk of bleeding, OTC PPIs are cost-effective.
- Aspirin plus prescription PPI was only cost-effective for the patients at the highest risk for upper GI bleeding, including much older patients.
- Starting PPI therapy at age 65 costs \$40,000 per year of life saved. Beginning PPI therapy at age 50 is estimated to cost \$80,000 per year of life saved.
- For patients at average risk for upper GI bleeding, starting prescription PPI therapy was only cost-effective if started later in life (age 80 or later).

Implications: Although studies have demonstrated its effectiveness in preventing upper GI bleeding in patients taking regular aspirin, PPI therapy ultimately will create an added cost to patients and insurers. This study addresses the question of whether the benefit of PPIs are worth this added cost. However, it is important to keep in mind that many patients also may not enjoy needing to take an additional medication every day, notes Saini, an issue not addressed by this study. Recent studies also have raised concerns about potential long-term side effects of PPIs – community acquired pneumonia and hip fractures caused by osteoporosis – although Saini says more study is need on this issue.

Methodology: The researchers used a computer model to simulate the lifetime risk of ulcer bleeding events in patients taking aspirin, using available literature to estimate the risk. Risk was modified based on whether or not a PPI was being concurrently taken by the patient. Then,

the total lifetime costs and life expectancy were tallied for those patients taking aspirin alone (PPI was only started if bleeding occurred), and patients taking daily aspirin plus a PPI. Based on those results, the cost per additional year of life saved under the PPI strategy was calculated.

Source: University of Michigan

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