

PPIs combined with oral anticoagulants reduce risk of gastrointestinal bleeding

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A Vanderbilt University Medical Center (VUMC) study published today in *JAMA* shows that patients already at higher risk for gastrointestinal bleeding gain a marked protection from this risk when they take a proton pump inhibitor (PPI) in combination with an oral anticoagulant.

Oral anticoagulants, which prevent blood clot formation, are among the most widely prescribed medications in the United States. They are predominantly used for patients with an irregular heart rate called atrial fibrillation, prosthetic heart valves and those with or at risk for deep vein thrombosis and cardiovascular diseases. Unfortunately, a major side effect of oral anticoagulants is the risk of significant bleeding, particularly upper gastrointestinal bleeding.

"The data suggest that if you give a population oral anticoagulants, 1 to 1.5 percent will have major upper gastrointestinal bleeding every year; that's a major side effect," said lead author Wayne Ray, Ph.D., professor of Health Policy at VUMC. "We undertook this study to clarify what can be done to reduce upper gastrointestinal bleeding risk. We had three questions: what is the role of PPIs in reducing this risk, how do the newer oral anticoagulants differ in terms of the risk of this side effect and how do those factors change when you look at individuals already at higher risk for gastrointestinal bleeding? Those at higher risk would be those who have a history of ulcer disease, as well as individuals using other medications that increase bleeding risk.

"We actually found a marked protective effect for PPI use that reduced

the risk of gastrointestinal bleeding by 34 percent. This risk reduction was most important among the highest risk patients where without a PPI the incidence of hospitalization for upper GI bleeding was 4 percent a year. Adding a PPI reduced that hospitalization rate to 2.8 percent per year."

For more than six decades, warfarin was the most commonly prescribed oral [anticoagulant](#), but its use has declined significantly as new oral anticoagulants have been approved by the Food and Drug Administration (FDA) that require less laboratory monitoring and have fewer drug and food interactions.

Ray and the same team of VUMC researchers published a 2016 study in the journal *Gastroenterology* that showed use of a PPI alongside warfarin reduced the risk of gastrointestinal bleeding. With many newer anticoagulants being prescribed and access to a large, national database of patient information, it made sense to undertake a large observational study including the newer drugs to measure and compare the co-therapy benefit, Ray said.

For the study, the [research team](#) pulled patient data from the Virtual Research Data Center, a database of the Centers for Medicare & Medicaid Services (CMS). The team identified 1.6 million patients who began oral anticoagulant therapy from 2011-2015. Patients were categorized based on those who also received PPIs and those who did not take PPIs. The incidence of hospitalizations for upper gastrointestinal bleeding was then compared. The team also compared the incidence of hospitalizations for this reason between four oral anticoagulant medications: apixaban, dabigatran and rivaroxaban and warfarin.

Among patients receiving oral anticoagulants, incidence of hospitalization for [upper gastrointestinal bleeding](#) was the highest for those taking rivaroxaban and lowest for apixaban. For each

anticoagulant, the incidence was lower among patients who also received PPI co-therapy.

"Oral anticoagulants can be extremely valuable in preventing an ischemic stroke, which is one thing you really do not want to have happen, and we can't lose sight of that," Ray said. "On the other hand, they have potentially very dangerous side effects. What we've done with this study is show that clinicians can focus on a high-risk population and significantly improve care for those patients with the addition of a PPI. Basically, before anticoagulant therapy is started it would be beneficial to complete a gastrointestinal workup to measure [patients'](#) existing risk factors and then tailor their therapy to take into account their risk status."

Provided by Vanderbilt University Medical Center

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