

Higher risk of bleeding in atrial fibrillation patients taking blood thinner dabigatran

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Alternative blood thinner increases risk of major bleeding

Pitt Public Health finds dabigatran riskier than warfarin



A University of Pittsburgh Graduate School of Public Health study in *JAMA Internal Medicine* gives new information on the blood thinner dabigatran when compared to warfarin. Credit: Nicole Davison/UPMC

Patients with atrial fibrillation who take the blood thinner dabigatran are at greater risk for major bleeding and gastrointestinal bleeding than those who take warfarin, according to a new study by researchers at the University of Pittsburgh Graduate School of Public Health.

The findings, based on Medicare claims data and published today in *JAMA Internal Medicine*, indicate greater caution is needed when prescribing [dabigatran](#) to certain high-risk [patients](#).

Atrial fibrillation, an arrhythmia in which the heart's upper chambers irregularly contract, can send tiny clots from the heart to the blood vessels in the brain, explained the study's senior author Yuting Zhang, Ph.D., associate professor and director of the Pharmaceutical Economics Research Group in Pitt Public Health's Department of Health Policy and Management. For that reason, these patients often are prescribed a blood thinner to limit clot formation with the aim of preventing strokes.

"Dabigatran was introduced in 2010 and, at the time of approval, it was the only available alternative to warfarin," Dr. Zhang said. "Warfarin dosing can be tricky and regular monitoring with blood tests is required, so doctors and patients were glad to have a drug that was easier to

manage. But some recent studies suggest that dabigatran is associated with a higher risk of [bleeding](#)."

To investigate that possibility, the study's first author, Inmaculada Hernandez, Pharm.D., Pitt Public Health, and the team looked back at pharmacy and medical claims data, which employ a unique identifier code rather than patient names, from 2010 and 2011 of a random national sample of Medicare beneficiaries. They tracked 1,302 dabigatran users and 8,102 warfarin users to see whether they experienced bleeding episodes, classifying the events as major, such as intracranial bleeding or gastrointestinal bleeding requiring a hospital or emergency room stay, or minor, such as gastrointestinal bleeding that was treated on an outpatient basis, or nose bleeds.

They also looked more closely at bleeding episodes in four high-risk subgroups: those who were 75 and older; African-Americans; those with [chronic kidney disease](#); and those with seven or more co-existing medical problems.

Medicare data showed that the incidence of [major bleeding](#) was 9 percent and of any bleeding was 32.7 percent in the dabigatran group and 5.9 percent and 26.6 percent, respectively, in the warfarin group. In other words, dabigatran users were 58 percent more likely to have a major bleed and 30 percent more likely to have any kind of bleed than those taking warfarin. African-Americans and patients with chronic kidney disease using dabigatran were about twice as likely to have a major bleed as those taking warfarin. In addition, dabigatran users were more likely than warfarin users to experience gastrointestinal or vaginal bleeding, or blood in the urine, joints or sputum. However, the dabigatran group had a lower risk for bleeding in the brain.

"These findings indicate that physicians should be cautious when prescribing dabigatran, particularly

to African-Americans and patients with kidney impairments," Dr. Hernandez said. "Also, the incidence of [gastrointestinal bleeding](#) was high in all the subgroups, so we recommend doctors explain to patients how to detect it so that it can be treated promptly."

"We plan to examine 2012 data to monitor the risk of stroke for patients on dabigatran, which is the primary indication for taking the blood thinner," Dr. Zhang said. "It's possible that for some patients a greater reduction in the risk of stroke will outweigh the higher risk of bleeding with dabigatran compared to warfarin."

More information: *JAMA Intern Med.* Published online November 3, 2014. [DOI: 10.1001/jamainternmed.2014.5398](#)

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