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High Risk of Bleeding with Dabigatran in AFib

According to a new study published in *JAMA Internal Medicine*, patients with atrial fibrillation who take the blood thinner dabigatran are at higher risk for major bleeding and gastrointestinal bleeding than those who take warfarin. The findings indicate that more caution is needed when prescribing dabigatran to certain high-risk patients, said researchers from the University of Pittsburgh Graduate School of Public Health.

Atrial fibrillation (AFib) is an irregular or rapid heartbeat that causes poor blood flow to the body. AFib can send tiny clots from the heart to the blood vessels in the brain, noted the study's senior author Yuting Zhang, PhD, associate professor and director of the Pharmaceutical Economics Research Group in Pitt Public Health's Department of Health Policy and Management. As such, these patients often are prescribed a blood thinner to reduce clot formation with the aim of preventing stroke.

When dabigatran was introduced in 2010, it served as the only available alternative to warfarin, Dr. Zhang narrated. "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 research team reviewed pharmacy and medical claims data, which use a unique identifier code rather than patient names, from 2010 and 2011 of a random national sample of Medicare beneficiaries. The team tracked 1,302 dabigatran users and 8,102 warfarin users to see whether they experienced bleeding episodes. The events were classified as major (i.e., intracranial bleeding or gastrointestinal bleeding requiring a hospital or emergency room stay) or minor (i.e., gastrointestinal bleeding that was treated on an outpatient basis, or nose bleeds).

The study's first author, Inmaculada Hernandez, PharmD, Pitt Public Health, said her team also scrutinised 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. The findings based on the Medicare data include the following:

- The incidence of major bleeding was nine percent and of any bleeding was 32.7 percent in the dabigatran group, versus 5.9 percent and 26.6 percent, respectively, in the warfarin group. Thus, 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 taking dabigatran were about twice as likely to have a major bleed as those using warfarin.
- 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 pointed out. "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."

The next step is to investigate 2012 Medicare data to monitor the risk of stroke for patients on dabigatran, which is the primary indication for taking the anticoagulant, 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," the professor added.

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