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ATRIAL FIBRILLATION

Risk of bleeding with dabigatran versus warfarin particularly high in CKD

In patients with atrial fibrillation, use of dabigatran etexilate mesylate was associated with a significantly higher risk of bleeding than was use of warfarin sodium. This new finding from a retrospective cohort study by Yuting Zhang and colleagues is in contrast to the results of the RE-LY trial, which showed no difference in the rates of major bleeding with these drugs and led to FDA approval of dabigatran in October 2010.

"Several months after its approval, the FDA received a large number of reports of severe dabigatran-related bleeding events," explains Zhang. "It was unclear whether dabigatran was associated with a higher bleeding risk than warfarin in real-world clinical practice. We used 2010–2011 Medicare data to investigate this question."

After adjustment for patient characteristics using a propensity score method, the incidence of major bleeding events was 9.0% (95% CI 7.8–10.2%) in the dabigatran group ($n = 1,302$) versus 5.9% (95% CI 5.1–6.6%) in the warfarin group ($n = 8,102$). Patients who received dabigatran had a higher risk of gastrointestinal bleeding, but a lower risk of intracranial haemorrhage, than those who received warfarin. Subgroup analysis showed that the risk of major bleeding with dabigatran was particularly high among African Americans and patients with chronic kidney disease (CKD).

"Our study only evaluated bleeding events in the first year after approval of dabigatran," says Zhang. "We anticipate that prescribing behaviours will change as physicians become familiar with this new drug so it is important to update our results using newer data." The researchers conclude that until more data on bleeding risks are available, dabigatran should be prescribed with caution.

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