

**ANTICOAGULATION THERAPY
BLEEDING NO WORSE
WITH NOVEL AGENTS**

Two new studies have demonstrated, in real-world populations, that anticoagulation therapy with dabigatran or rivaroxaban has similar risks of gastrointestinal bleeding to warfarin treatment, although the relative risks could vary according to patient age.

Novel anticoagulants have potential benefits, such as simplified dosing, and clinical trials have demonstrated their noninferiority relative to warfarin for prevention of stroke and systemic embolism, but also suggested higher rates of gastrointestinal bleeding with the novel agents. Two large, retrospective studies of bleeding rates have now been conducted, addressing the nonrepresentative nature of the clinical trial cohorts. The studies used information from US administrative claims databases, with propensity score weighting or matching to control for differences in patient characteristics between treatment groups. Neither study reported a significant difference in gastrointestinal bleeding rates with novel anticoagulants versus warfarin.

In one study, 4,907 patients receiving dabigatran, 1,649 receiving rivaroxaban, and 39,607 receiving warfarin were compared. Adjusted hazard ratios for gastrointestinal bleeding were 1.21 and 0.98 for dabigatran and rivaroxaban, respectively, relative to warfarin. No significant differences were seen between age groups, despite an apparently higher risk of bleeding with dabigatran than with warfarin in patients aged <65 years.

In the other study, 8,578 patients receiving dabigatran, 16,253 receiving rivaroxaban, and 67,985 receiving warfarin were compared. Adjusted hazard ratios for gastrointestinal bleeding for dabigatran and rivaroxaban relative to warfarin were 0.79 and 0.93 in patients with atrial fibrillation (AF), and 1.14 and 0.89 in those without AF. Risks of bleeding increased with age, and the increase was greater for novel anticoagulants. With either dabigatran or rivaroxaban, the risk was lower than with warfarin in patients aged ≤ 75 years, but higher in those aged ≥ 76 years.

These results suggest that further work is needed to test the association between bleeding risk and patient age, but overall, novel anticoagulants confer similar risks of gastrointestinal bleeding to warfarin.

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Original articles Chang, H.-Y. *et al.* Risk of gastrointestinal bleeding associated with oral anticoagulants: population based retrospective cohort study. *BMJ* 350, h1585 (2015) | Abraham, N. S. *et al.* Comparative risk of gastrointestinal bleeding with dabigatran, rivaroxaban, and warfarin: population based cohort study. *BMJ* 350, h1857 (2015)