

The ODPRN conducted a population-based study on direct oral anticoagulants (DOAC) and the risk of major hemorrhage in elderly patients with chronic kidney disease (CKD). Key information, policy recommendations, and details from the study are highlighted

## DOACs may confer similar hemorrhagic risks relative to warfarin in elderly patients with CKD

*No association found between the use of DOACs (dabigatran or rivaroxaban), as compared to warfarin, and major hemorrhage.*

### Why did we do this study?

To determine the safety of DOACs among elderly patients with CKD. The Research Minute summarizes key points from a research study conducted by the ODPRN.

### What were we investigating?

In this study we investigated whether use of dabigatran or rivaroxaban is associated with a higher risk of major hemorrhagic events as compared to warfarin in elderly patients with CKD

### Where can I find more information?

The full study is available [here](#)

### About ODPRN

We leverage cutting-edge research methodology and rapidly incorporate findings into policy reports for decision-makers on real-world drug utilization, safety, effectiveness, and costs.

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### KEY POINTS

- Exposure to DOAC's (dabigatran or rivaroxaban) was not associated with a higher risk of hemorrhagic events compared to warfarin among elderly patients with CKD.
- Stratified analyses according to the prescribed dose of dabigatran and rivaroxaban yielded similar results.

### CLINICAL IMPLICATIONS

- Although we have demonstrated that dabigatran and rivaroxaban possess a similar safety profile as warfarin in patients with CKD, caution when prescribing these agents is still advisable as CKD is associated with abnormalities in hemostasis, and a higher risk of acute kidney injury, the onset of which may be rapid and unpredictable. If clinicians choose to prescribe a DOAC to a patient with CKD, close monitoring of kidney function for evidence of progressive decline is warranted.
- Further trials of DOACs focusing on the CKD population will help clarify the true efficacy and safety of these drugs.

### STUDY DETAILS

- The ODPRN conducted a population-based nested case-control study among residents of Ontario, Canada, aged 66 years and older with a history of CKD between April 1, 2006 and March 31, 2013.
- We identified 237,409 patients with CKD, of whom 4470 (1.9%) experienced a major hemorrhage. We matched these cases to 14,460 control patients. After matching, there were 419 (2.2%) patients exposed to dabigatran, 151 (0.8%) exposed to rivaroxaban, and 18,360 (97%) exposed to warfarin within 60 days preceding the index date.
- The use of dabigatran or rivaroxaban was not associated with a statistically significantly elevated risk of major hemorrhage compared to warfarin (adjusted odds ratio (aOR) 1.15, 95% confidence interval (CI) 0.91-1.45 for dabigatran, aOR 1.22; 95% CI 0.83-1.79 for rivaroxaban).
- After conducting a sensitivity analysis, neither low nor high daily doses of dabigatran and rivaroxaban were associated with a statistically significant risk of major hemorrhage compared to warfarin.