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## Gastrointestinal Safety of Direct Oral Anticoagulants: a Large Population-based Study

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DOI: <http://dx.doi.org/10.1053/j.gastro.2016.12.018>



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### Abstract

### Background & Aims

Direct oral anticoagulant (DOAC) agents increase the risk of gastrointestinal (GI) bleeding. We investigated which DOAC had the most favorable GI safety profile and compared differences among these drugs in age-

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related risk of GI bleeding.

## Methods

We conducted a retrospective, propensity-matched study using administrative claims data from the OptumLabs Data Warehouse of privately insured individuals and Medicare Advantage enrollees. We created 3 propensity-matched cohorts of patients with non-valve atrial fibrillation with incident exposure to dabigatran, rivaroxaban, or apixaban, from October 1, 2010 through February 28, 2015. We compared data on rivaroxaban vs dabigatran for 31,574 patients, data on apixaban vs dabigatran for 13,084 patients, and data on apixaban vs rivaroxaban for 13,130 patients. Cox proportional hazards models, stratified by age, were used to estimate rates of total GI bleeding.

## Results

Baseline characteristics were well balanced among sub-cohorts. GI bleeding occurred more frequently in patients given rivaroxaban than dabigatran (hazard ratio [HR], 1.20; 95% CI, 1.00–1.45). Apixaban was associated with a lower risk of GI bleeding than dabigatran (HR, 0.39; 95% CI, 0.27–0.58;  $P < .001$ ) or rivaroxaban (HR, 0.33; 95% CI, 0.22–0.49;  $P < .001$ ). Rates of events for all DOACs increased among patients 75 years or older. Apixaban had a lower risk of association with GI bleeding in the very elderly than dabigatran (HR, 0.45; 95% CI, 0.29–0.71) or rivaroxaban (HR, 0.39; 95% CI, 0.25–0.61). Median times to GI bleeding were less than 90 days for apixaban and rivaroxaban and less than 120 days for dabigatran.

## Conclusions

In a population-based study of patients receiving DOAC agents, we found apixaban had the most favorable GI safety profile and rivaroxaban least favorable. GI bleeding events among patient taking DOACs increased with age; the risk was greatest among persons  $\geq 75$  years old. Apixaban had the most favorable GI safety profile among all age-groups.

### Key Words:

[Gastrointestinal hemorrhage](#), [comparative safety](#), [anticoagulant](#), [atrial fibrillation](#)

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### Disclosures:

No authors report any conflict of interest.

### Writing Assistance:

This study was funded by the Mayo Clinic Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery. The design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication were solely the responsibility of the authors listed. Dr. Yao had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis

### Authors' Contributions:

Study Concept and design: Drs. Abraham and Shah

Acquisition, analysis of data: Drs. Shah, Abraham, Yao, and Ms. Sangaralingham. Dr. Yao had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Interpretation of data: Drs. Abraham, Shah, Yao, Noseworthy, and Ms. Sangaralingham

Drafting of the manuscript: Drs. Abraham, Shah and Ms. Sangaralingham

Critical revision of the manuscript for important intellectual content: All authors

Statistical analysis: Dr. Yao and Ms. Sangaralingham

Study supervision: Drs. Abraham and Shah

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