

# DSEN ABSTRACT

## Direct oral anticoagulants in venous thromboembolism

A study conducted by the Canadian Network for Observational Drug Effect Studies (CNODES)

### Summary

- Compared to warfarin, treatment of newly-diagnosed VTE with a DOAC was not associated with an increased risk of major bleeding or all-cause mortality.

### Key messages

- These findings provide evidence for the safety of DOACs in the treatment of VTE in a real-world setting.
- Physicians may not need to consider the risk of major bleeding when prescribing a DOAC instead of warfarin.

### Project Lead & Team

- Brenda Hemmelgarn, MD, PhD, FRCP(c)
- Team members [available here](#)

### Link to publication

- Jun et al. BMJ. 2017. [doi: 10.1136/bmj.j4323](https://doi.org/10.1136/bmj.j4323).

### What is the issue?

- Direct oral anticoagulants (DOACs) are used in the treatment of venous thromboembolism (VTE). They offer advantages over the use of warfarin, with no need for regular monitoring and dose adjustment.
- Clinical trials have shown that DOACs have a comparable efficacy to warfarin, however their safety in a real-world setting remains uncertain.

### What was the aim of the study?

- CNODES evaluated the safety (major bleeding and all-cause mortality) of DOAC (dabigatran, apixaban or rivaroxaban) use compared with warfarin use for the treatment of VTE.

### How was the study conducted?

- CNODES undertook a retrospective, propensity score-matched cohort study using health records from 5 Canadian provinces (Alberta, Manitoba, Ontario, Quebec and Saskatchewan) and the US IBM MarketScan® database.
- The study cohort included 59,525 adult patients with a new diagnosis of VTE and a prescription for a DOAC or warfarin within 30 days of the diagnosis.
- The outcomes were major bleeding requiring hospital admission or emergency department visit and all-cause mortality within 90 days of treatment initiation.
- Hazard ratios (HR) and 95% confidence intervals (CI) were estimated and pooled across sites using meta-analysis.

### What did the study find?

- Among patients with VTE, treatment with DOACs compared to warfarin was not associated with an increased risk of major bleeding (HR 0.92; 95% CI: 0.82 to 1.03) or all-cause mortality (HR 0.99; 95% CI: 0.84 to 1.16).
- Results were consistent for patients with and without chronic kidney disease, across all age groups, and for men and women.
- These findings provide reassurance as to the risk of major bleeding and all-cause mortality with DOACs in a real-world setting.

This research was funded by CIHR – Drug Safety and Effectiveness Network and conducted by CNODES:



For more information, please contact [info@cnodes.ca](mailto:info@cnodes.ca).