



National Trends in Ambulatory Oral Anticoagulant Use

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ABSTRACT

BACKGROUND: Four direct oral anticoagulants (DOACs) have been brought to market for the treatment of nonvalvular atrial fibrillation and venous thromboembolism. Many forces, including numerous positive trial results, emerging safety concerns, marketing, and promotion, may shape DOAC adoption by providers. However, relatively little is known regarding their ambulatory utilization compared with warfarin, as well as the degree to which they have decreased under-treatment of atrial fibrillation.

METHODS: We used the IMS Health National Disease and Therapeutic Index, a nationally representative audit of outpatient office visits, to estimate the use of warfarin and DOACs between 2009 and 2014.

RESULTS: Overall, visits with anticoagulation use increased from 2.05 (95% confidence interval [CI], 1.82-2.27) to 2.83 (95% CI, 2.49-3.17) million (M) quarterly visits ($P < .001$). Of these, DOAC use has grown to 4.21M (95% CI, 3.63M-4.79M; 38.2% of total) treatment visits in 2014 since their introduction in 2010. Use of all oral anticoagulants in treatment visits for atrial fibrillation has increased from 0.88M (95% CI, 0.74M-1.02M) to 1.72M (95% CI, 1.47M-1.97M; $P < .001$), with similar DOAC and warfarin use in 2014. Atrial fibrillation visits with anticoagulant use increased from 51.9% (95% CI, 50.4%-53.8%) to 66.9% (95% CI, 65.0%-69.3%) between 2009 and 2014 ($P < .001$). In 2014, rivaroxaban was the most commonly prescribed DOAC for atrial fibrillation (47.9% of office visits), followed by apixaban (26.5%) and dabigatran (25.5%).

CONCLUSIONS: Direct oral anticoagulants have been adopted rapidly, matching the use of warfarin, and are associated with increased use of oral anticoagulation for patients with atrial fibrillation.

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Thromboembolic events associated with atrial fibrillation and venous thromboembolism are leading causes of morbidity and mortality worldwide.¹⁻³ Prevention and treatment of thromboembolism is best achieved with oral anticoagulant

therapy. Vitamin K antagonists (primarily warfarin) have been the traditional oral anticoagulant for decades. However, 4 direct oral anticoagulants (DOACs)—dabigatran, rivaroxaban, apixaban, and edoxaban—were introduced sequentially

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into clinical practice beginning in 2010.⁴ Despite their costs, these agents have achieved popularity among both patients and providers because of their efficacy, ease of use, and favorable safety profile. As such, they are often first-line therapy for stroke prophylaxis in the context of atrial fibrillation, as well as the treatment and prevention of venous thromboembolism.

Despite the clear benefit of anticoagulation for atrial fibrillation and venous thromboembolism and the growing enthusiasm for DOACs, clinicians and public health officials remain concerned about potential underutilization of oral anticoagulants for these conditions.⁵ This has important clinical implications for the estimated 3 million patients with atrial fibrillation and approximately 75,000 patients diagnosed annually with venous thromboembolism.⁶ To date, longitudinal nationwide analyses of oral anticoagulation utilization have not demonstrated any meaningful change in the underutilization of anticoagulant therapy for atrial fibrillation patients.^{1-3,7}

To establish the utilization of anticoagulants and its impact on treatment for atrial fibrillation and venous thromboembolism, we examined a nationally representative, contemporary audit of commercially available oral anticoagulants between 2009 and 2014. In addition to extending prior work that was limited to examining the early market experience after dabigatran's US Food and Drug Administration (FDA) approval,⁷ we explored the impact of 2 additional DOACs on anticoagulant use. We also examined the change in percentage of office visits for atrial fibrillation where an anticoagulant was prescribed. We hypothesized that DOAC use would replace warfarin use for the treatment of atrial fibrillation and venous thromboembolism and that the total number of atrial fibrillation patients receiving oral anticoagulants would increase.

METHODS

Data Source

The IMS Health National Disease and Therapeutic Index (NDTI) is an ongoing survey of office-based physicians in the United States that provides nationally representative data on the patterns and treatment of disease. The database has been described in detail in previous studies.⁷⁻¹⁰ Briefly, the NDTI prospectively collects office-based clinical information from approximately 4800 physicians identified through a random audit of the American Medical Association and American Osteopathic Association databases. The NDTI data include diagnosis, physician specialty, geographic region, patient age, and gender. The NDTI survey captures

information on all clinic visits during 2 consecutive working business days per quarter, generating approximately 350,000 annual contract records. The NDTI also includes physician–patient interactions via phone call and in skilled nursing facilities (approximately 15% of all visits), which were excluded from our analysis. For each office-based encounter, all diagnosed conditions and the specific medications used or documented for each diagnosis are recorded. Each medication record within the NDTI is linked to a 6-digit taxonomic code, similar to the International Classification of Diseases, Tenth Revision, Clinical Modification, that captures diagnostic information. Using the sampling frame and weights, national estimates of office-based practice patterns can be extrapolated from NDTI data.⁷⁻¹⁰

CLINICAL SIGNIFICANCE

- The number of office visits with anticoagulant use is increasing, largely driven by new visits with direct oral anticoagulant use in atrial fibrillation patients.
- Currently, direct oral anticoagulants and warfarin are used in equal numbers of office visits for atrial fibrillation.
- Overall, oral anticoagulants are being used in an increasing percentage of office visits for atrial fibrillation.

Analyses

Our primary unit of analysis was a treatment visit, defined as an office visit in which an oral anticoagulant was used. A single medication can produce more than 1 treatment visit during a single clinical encounter if that medication is used for multiple indications. We limited our analysis to treatment visits for warfarin and the 3 DOACs available during the study period (dabigatran, rivaroxaban, and apixaban) for atrial fibrillation and venous thromboembolism in patients aged ≥ 18 years. Analysis was performed on aggregated quarterly office visit estimates, because individual patient-level data were not available. Because we are interested in outpatient treatments, we excluded injectable anticoagulants from our analyses. The institutional review board of the University of Michigan Medical School assessed this study as not regulated and waived the requirement for informed consent.

When assessing indications for oral anticoagulant use, we explored common cardiovascular conditions, specifically atrial fibrillation (including atrial flutter) and venous thromboembolism, as were coded in the visit diagnosis and linked to the use of a specific medication. Although the DOACs are FDA-approved only for nonvalvular atrial fibrillation, the NDTI does not allow for reliable distinction between valvular atrial fibrillation and nonvalvular atrial fibrillation.

We used descriptive statistics to examine national estimates of treatment visits and dispensed medications between April 2009 and December 2014. We also conducted analyses of treatment visits after stratifying visits by the indication for anticoagulation and for age ≥ 65 years. Reported data include market share analysis, defined by the proportion of observed visits associated with a specific oral anticoagulant (or class) divided by the total observed visits

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