Medicine by the Numbers

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Rivaroxaban vs. Warfarin for Anticoagulation in Patients with Atrial Fibrillation Undergoing Ablation and Cardioversion

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RIVAROXABAN VS. WARFARIN FOR ANTICOAGULATION IN PATIENTS WITH ATRIAL FIBRILLATION UNDERGOING ABLATION OR CARDIOVERSION

Benefits Harms

433 patients treated with rivaroxaban to prevent one stroke

Major and minor bleeding complications were similar

629 patients treated with rivaroxaban to prevent one thromboembolic event

Details for This Review

Study Population: Adults with atrial fibrillation undergoing a catheter ablation or cardioversion who received anticoagulation with rivaroxaban (Xarelto) or vitamin K antagonists (such as warfarin [Coumadin])

Efficacy End Points: Prevention of thromboembolism (stroke, transient ischemic attack, systemic embolism, or pulmonary embolism)

Harm End Points: Major and minor bleeding complications

Narrative: Atrial fibrillation is a common diagnosis (2.7 to 6.1 million adults in the United States¹), which is typically treated with anticoagulation to prevent thromboembolism. In particular, patients undergoing catheter ablation or cardioversion are at an increased risk of complications (thromboembolism and bleeding) caused by the activation of the clotting cascade in addition to the invasive nature of the techniques used.² The development of new anticoagulants over the past couple of years has raised questions about the optimal choice for treatment. Evaluating these new anticoagulants is complicated because the incidence of thromboembolism

and bleeding is thought to be near or below 1%, requiring a large collection of data to effectively compare medications.³

A 2015 high-quality meta-analysis used data from 15 studies with a total of 8,872 patients undergoing catheter ablation or cardioversion and receiving rivaroxaban or a vitamin K antagonist. There were significantly fewer overall thromboembolic events (number needed to treat [NNT] = 629) and strokes (NNT = 433) in those receiving rivaroxaban compared with those receiving a vitamin K antagonist. Major and minor bleeding complications were noted to be statistically equivalent, occurring in 115 (4%) of those receiving rivaroxaban vs. 207 (4.9%) of those receiving a vitamin K antagonist (odds ratio = 0.84; 95% confidence interval, 0.66 to 1.08).3

Caveats: Despite a statistically significant advantage of rivaroxaban over vitamin K antagonists in the prevention of thromboembolism, further discussion is required to address the clinical significance of this finding given the relatively large NNT. With the incidence of major and minor bleeding complications being similar between the therapies, the concern for a higher complication rate with rivaroxaban because of a lack of a proven reversible agent is negligible. Cost is also a key factor when comparing these medications and was addressed in a recent study comparing rivaroxaban and vitamin K antagonistis for patients with nonvalvular atrial fibrillation. The study found that the higher cost of rivaroxaban is offset by the increased cost of initial hospitalization and longterm use of a vitamin K antagonist.4 Other considerations include diet restrictions,

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increased dosing complications, and the number of clinical visits for patients receiving a vitamin K antagonist. Considering these factors, rivaroxaban appears to be a reasonable alternative, despite a marginal NNT of 433 to prevent one stroke.

Although this study addressed the key adverse effects of major and minor bleeding disorders, it did not separate or clarify severity of the event, and in particular did not address death rate secondary to these complications.

This series is coordinated by Dean A. Seehusen, MD, MPH, *AFP* Contributing Editor, and Daniel Runde, MD, from the NNT Group.

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REFERENCES

- 1. January CT, Wann LS, Alpert JS, et al. 2014 AHA/ACC/ HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society [published correction appears in *J Am Coll Cardiol*. 2014; 64(21):2305-2307]. *J Am Coll Cardiol*. 2014;64(21): e1-e70
- Oral H, Chugh A, Ozaydin M, et al. Risk of thromboembolic events after percutaneous left atrial radiofrequency ablation of atrial fibrillation. *Circulation*. 2006; 114(8):759-765.
- 3. Nairooz R, Sardar P, Pino M, et al. Meta-analysis of risk of stroke and thrombo-embolism with rivaroxaban versus vitamin K antagonists in ablation and cardioversion of atrial fibrillation. *Int J Cardiol.* 2015;187:345-353.
- 4. Laliberté F, Cloutier M, Crivera C, et al. Effect of rivaroxaban versus warfarin on health care costs among non-valvular atrial fibrillation patients: observations from rivaroxaban users and matched warfarin users [published correction appears in Adv Ther. 2015;32(4):387]. Adv Ther. 2015;32(3):216-227. ■