

understands the risks, benefits and alternatives to surgery — information a surgeon should convey during the decision-making process.

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New oral anticoagulants

A *CMAJ* letter¹ from a “little cheese” family physician about new oral anticoagulants versus warfarin, and the response² from three “big cheese” academic specialists show that readers and authors of guidelines do not always agree.

The Canadian Cardiovascular Society's 2014 update of its *Guidelines for the Management of Atrial Fibrillation*³ unsystematically strengthened its 2012 recommendation that dabigatran, rivaroxaban, apixaban, and edoxaban (when licensed) are preferred over warfarin for most patients with atrial fibrillation.

The guideline authors note the absence of published randomized trials directly comparing the four new anticoagulants, and assure readers that “it is unlikely that any will be conducted in the near future.”³ The guideline emphasizes that indirect comparisons between new oral anticoagulants limit our ability to draw inferences on whether any are superior or inferior, and that “any differences in efficacy that might exist among the NOACs [new oral anticoagulants], and even the difference in efficacy between warfarin and each of the NOACs, is very small compared with the reduction of stroke with any OAC [oral anticoagulant] compared with no OAC.”

Can we learn from the example of cancer or combined antiretroviral therapy, where comparative effectiveness trials have led to preferred regimens based upon randomized controlled trials?

Not all clinicians have jumped on the bandwagon. That's likely because of concern that warfarin management

in the control arms of the principal randomized controlled trials was suboptimal according to the US Food and Drug Administration's medical reviewers; we cannot reverse the anticoagulant effect of the new oral anticoagulants or monitor anticoagulant activity; and irregularities in the conduct of the randomized controlled trials may have compromised the apparent evidence.⁴⁻⁶

Atrial fibrillation is estimated to affect 350 000 Canadians.⁷ Canada could conduct a randomized controlled trial comparing the new oral anticoagulants with warfarin in suitable, comprehensively informed patients with nonvalvular atrial fibrillation and for additional indications for anticoagulation such as venous thromboembolism. With central randomization, the trial could be conducted in the context of usual clinical care, using linked administrative datasets to ascertain the most important clinical outcomes, including death, disability from stroke or intracranial hemorrhage, total serious adverse events and clinically important vascular events. Such a trial could be conducted at a trivial cost when compared to the benefits to health and quality of care. What are we waiting for?

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Competing interests: Thomas L. Perry was a pain expert for plaintiff lawyers, US Neurontin lawsuit 2008–2010, an expert consultant for a proposed class action lawsuit against Purdue Pharma (OxyContin) promotion, and a participant in an audit of RE-LY trial (dabigatran) paid by multidistrict litigators (USA). He was also a paid consultant to a multidistrict litigation consortium in the United States on an independent audit of the RE-LY trial (dabigatran). His role was principally to re-adjudicate (blinded) clinical events reported in the trial. No other competing interests were declared.

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Letters to the editor

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CORRECTION

Mobitz II

A practice article that appeared in the Jan. 6, 2015, issue of *CMAJ* contains an error. Box 1, bullet 6 should read as follows:

- Risk factors on electrocardiography, such as:
 - Bifascicular, Mobitz II second-degree, or complete (third-degree) heart block.

Reference

1. Soong C, Chen BH, Wong BM. A 62-year-old woman with syncope. *CMAJ* 2015;187:48-9.

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