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Full Length Article

Development and validation of a decision aid for choosing among antithrombotic agents for atrial fibrillation☆

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ABSTRACT

Background: Multiple antithrombotic agents are available for stroke prevention in atrial fibrillation (AF). A decision aid can assist patients in making informed decisions that best serves their needs.
Objective: To validate a decision aid to assist patients in choosing between antithrombotic agents (antiplatelets, warfarin, direct-acting oral anticoagulants (DOACs)) for AF.
Methods: Patients (60 years or older) were recruited for this prospective study. The decision aid presented descriptions related to AF, then charts portraying important outcomes for comparisons between 1) no treatment, aspirin and anticoagulants, 2) warfarin versus DOACs, and 3) DOAC versus DOAC. The primary outcome was confidence in making treatment decisions. The secondary outcomes included change in knowledge scores, ratings of clarity, helpfulness and comprehensiveness.
Results: Eighty-one patients (mean age 75.2 [SD 7.5], 77% taking an anticoagulant) participated. After using the decision aid, mean decisional conflict score was low at 7.2 [SD 10.8] on a scale from 1 to 100. Mean knowledge score (total possible 10) improved from 7.4 [SD 1.7] to 9.3 [SD 1.0] ($p < 0.001$). The mean helpfulness score in making a treatment choice was high at 6.2 [SD 0.9] on a scale from 1 to 7. No participant found the decision aid difficult to understand. Information in the decision aid was rated as good or excellent in terms of clarity and comprehensiveness.
Conclusions: Our decision aid addresses a key medication safety gap – assisting patients to participate in shared decisions about anticoagulation. Future research is required to evaluate how decision aids influence actual choices and clinical outcomes.

1. Background

Atrial fibrillation (AF) is an age-related cardiac arrhythmia that affects approximately 350,000 older Canadians [1–2]. Antithrombotic agents are routinely prescribed for AF to reduce the risk of stroke, systemic embolism and death [3]. Warfarin has been the dominant anticoagulant drug for the past 60 years and is highly effective, reducing the risk of stroke by 68% [4]. Direct acting oral anticoagulant drugs (DOACs) – dabigatran, rivaroxaban and apixaban – have been approved, and shown to be similar to warfarin in terms of efficacy and safety for anticoagulation. Warfarin requires regular laboratory monitoring to ensure a therapeutic anticoagulation level, and causes slightly more intracranial bleeding (number needed to harm = 271) [5] than DOACs but is administered once daily and can be used in all anticoagulation situations including renal disease [6–7]. DOACs have no laboratory monitoring requirement for anticoagulant effect, but lack readily available antidotes if bleeding occurs, several require twice daily dosing and withdrawal in severe renal impairment [8]. Aspirin is an inferior antithrombotic drug for stroke prevention in AF, but is preferred to anticoagulation by some patients because of its familiarity [9].

Patient decision aids are tools that provide important information on healthcare options to assist patients in making an informed decision [10]. They help patients clarify their values in relation to their decision and decide on the importance they place on the relative benefits, harms, and practical considerations based on available scientific evidence before making a choice that is best for them. A Cochrane systematic review on patient decision aids concluded that these aids help patients be more confident and comfortable with their chosen treatment decision [11]. Our previous studies of patient decision aids for anticoagulants showed positive results in terms of their helpfulness in decision-making [9], [12–13]. Given the increased number of anticoagulant options available, a more complex decision aid is needed to

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compare all the options together. The objective of this study was to develop and validate a patient decision aid to assist patients in choosing between different antithrombotic medications for AF.

2. Methods

This study was approved by the Hamilton Integrated Research Ethics Board (Project Number 14-308).

2.1. Development of decision aid

We updated our previous patient decision aid - which included only warfarin and dabigatran as options – to encompass more antithrombotic treatment options [13]. To do this, we reviewed Phase 3 trial reports of each DOAC, the Health Canada and FDA reviews, an indirect meta-analysis of comparative effectiveness, safety and cost-effectiveness of DOACs versus warfarin, and network meta-analysis and randomized controlled trials of aspirin versus warfarin, placebos and each DOAC [1,8], [14–22]. This information was used to revise and add on to the decision aid's descriptions of AF, stroke, bleeding, and the benefits, harms and practicalities of use of each pharmacologic antithrombotic agent. In consultation with experts in stroke neurology, cardiology, hematology and thrombosis, clinical pharmacology, internal medicine, epidemiology and statistics – we further revised the decision aid and developed additional summary comparison charts that portrayed information on important outcomes for comparisons between 1) no treatment, aspirin and anticoagulants, 2) warfarin and DOACs, and 3) dabigatran, rivaroxaban and apixaban [1,8], [14–22]. Information in the decision aid was presented in various formats including words, numbers and diagrams. The decision aid was vetted against the International Patient Decision Aid Standards (IPDAS) standard criteria relating to the content, development process and effectiveness of the decision aid [23]. This meant clarifying options, their advantages and disadvantages, encouraging reflection on individual values, using a systematic development process, summarizing best evidence in plain language with supportive graphical representation, and measurement of informed decision-making according to preferences. Pretesting with fifteen patients led to further refinement of the decision aid. (See Figs. 1 and 2 for sample pages from the decision aid. The full decision aid can be accessed here: https://rsjh.ca/holbrook/NOACs_warfarin_decision_aid_booklet_chart_May26_16.pdf.)

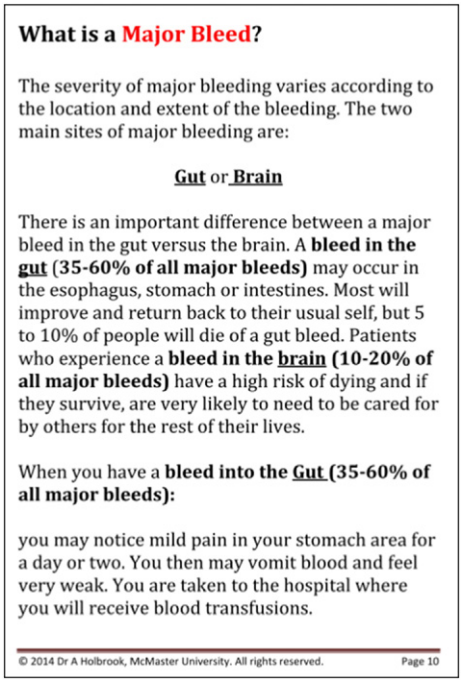

Fig. 1. Sample page from decision aid.

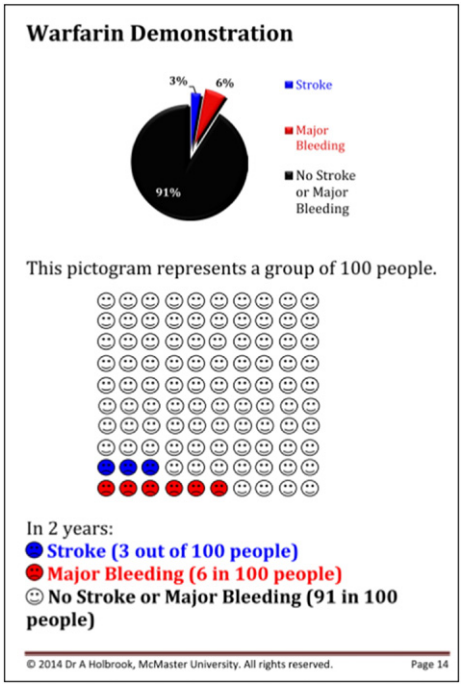

Fig. 2. Sample page from decision aid.
Link to full decision aid: https://rsjh.ca/holbrook/NOACs_warfarin_decision_aid_booklet_chart_May26_16.pdf.

2.2. Participants

Participants were recruited from cardiology and thrombosis clinics, in addition to inpatient hospital wards in Hamilton, Ontario using a convenience sampling strategy. Potential participants were informed of the project's purpose verbally by the attending physician or via a letter mailed by the clinic. Subsequently, they were introduced to the research interviewer who described the study in more detail and obtained written informed consent. Adults aged 60 years or older who could read and understand English and demonstrate adequate cognition were included in the study. Cognition was assessed by a validated orientation-memory-concentration test (OMCT), where an error score of 6 or less out of 28 on the OMCT test indicated acceptable cognition [24]. From our sample size calculation, we estimated that at least 62 patients would be needed in this single case series to give us confidence in a low decisional conflict score, given a margin of error of 5, a 95% confidence interval and a standard deviation of 20.

2.3. Interview process

Participants who passed the cognition test proceeded to the full interview. Patient demographics, current medications, anticoagulants and antiplatelet agents current or past, and medical conditions were obtained. This information was used to calculate their personalized risk of stroke and risk of bleeding using the CHA_2DS_2-VASc and HAS-BLED calculators respectively. Participants then completed a short knowledge test to assess their baseline knowledge on AF and anticoagulants. We have used this knowledge test in previous decision aid studies and found it to be responsive to the decision aid, as it did show an improvement in knowledge [9], [12–13]. The previously validated Oral Anticoagulation Knowledge (OAK) test was too long for our purposes and did not cover questions pertaining to the newer DOACs [25]. At