

Development and Validation of a Decision Aid for Choosing Among Anticoagulants for Atrial Fibrillation

**A studentship Project
Funded in part by the Canadian Patient Safety Institute**

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Project Summary

Introduction: Oral anticoagulants are high priority medications as they are the leading cause of emergency visits and hospitalizations for adverse drug events in older adults in Canada. Warfarin is the commonly used anticoagulant drug for the past 60 years, however new oral anticoagulant drugs (NOACs), dabigatran, rivaroxaban and apixaban, have recently entered the market. The proliferation of anticoagulation choice has made it more challenging for healthcare providers and patients to make informed decisions and may have increased medical errors and adverse events. A patient decision aid is a tool that provides information regarding a health condition and its complications, and the treatment options available with their associated benefits and harms. It is intended to increase patient knowledge and assist them in making an informed decision. Recent systematic reviews show that decision aids help patients feel more informed about their choices and have more realistic expectations of potential benefits and harms.

Objectives: The study objectives were to develop and validate a patient decision aid comparing 1) no treatment, aspirin and anticoagulants, 2) warfarin and NOACs, and 3) dabigatran, rivaroxaban and apixaban, in terms of knowledge transfer, comprehensiveness and helpfulness.

Methods: The decision aid was developed in accordance with the International Patient Decision Aid Standards (IPDAS) standard criteria, reviewed by experts in the field and pre-tested among patients. This was a prospective case series study involving adult patients ≥ 60 years of age with. Participants completed an atrial fibrillation knowledge questionnaire before and after completing the decision aid and made a treatment choice. The primary outcome was confidence in making

decisions regarding their treatment, using a validated decisional conflict scale. Secondary outcomes included change in knowledge scores and ratings of clarity, helpfulness and comprehensiveness.

Results: In this interim analysis, 41 patients (mean age 74.9 [SD 8.7], 29.3% female, 87.8% taking anticoagulant) were included. After using the decision aid, the mean decisional conflict score was low at 4.3 (SD 7.1) on a scale from 1 to 100. The mean knowledge score was 7.7 (SD 1.4) out of a total score of 10 and improved to 9.4 (SD 0.8) following the use of the decision aid ($p < 0.001$). The mean helpfulness score of the decision aid in making a treatment choice was high at 6.42 on a scale from 1 to 7. Only one participant (2.6%) found the information presented in the decision aid difficult to understand. Information on AF, stroke, bleeding, benefits, harms and the summary drug comparison charts was rated as good or excellent in terms of clarity and comprehensiveness.

Discussion: Pending completion and analysis of the full study, we have successfully validated a decision aid for patients to make informed, shared decisions with their physicians regarding anticoagulation. Next steps will be to investigate whether use of the decision aid changes anticoagulation decisions, adherence or outcomes.

Purpose / Objectives / Research Questions

Atrial fibrillation, affecting an estimated 350,000 Canadians, is the most common chronic cardiac arrhythmia and is thought responsible for approximately one-third of all strokes^{1,2}. Anticoagulants are one of the most effective medications known, in that they reduce stroke risk by 64%, resolve life-threatening venous thromboemboli, and reduce mortality by 26%³. Warfarin is the commonly used anticoagulant drug for the past 60 years⁴, however new oral anticoagulant drugs (NOACs), dabigatran, rivaroxaban and apixaban, have recently entered the market. Unfortunately all anticoagulants have narrow therapeutic indices, therefore cause significant harm particularly related to bleeding⁵. Warfarin requires regular laboratory monitoring to assess the degree of anticoagulation, but the monitoring is a useful adherence assessment and can be infrequent⁶. NOACs do not require (or benefit from) this type of monitoring but each (dabigatran, rivaroxaban and apixaban) to variable amount has trouble with accumulation with renal impairment, gastrointestinal distress leading to discontinuation, lack of an antidote for bleeding, and twice daily dosing⁷.

Oral anticoagulants are the highest medication safety priority for two main reasons. First, more than 5 million prescriptions for oral anticoagulants are dispensed annually in Canada, putting them in the ‘top 20’ list of most prescribed medications⁸. Second, anticoagulants are the leading cause of emergency visits and hospitalizations for adverse drug events in older adults in Canada and the United States⁹.

With the recent surge of anticoagulation choices, it has become very confusing for health care providers and patients to make decisions about anticoagulation and monitoring. However,

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evaluating this is not easy as there is little absolute difference between the new drugs - compared to one another and compared to warfarin¹. At present, patients with atrial fibrillation are being asked to take an anticoagulant, a medication associated with significant potential harm, then digest the small differences among the 4 drugs in important clinical outcomes, understand the commitment they are taking on in terms of lifestyle - other medications, food, activity, blood monitoring, etc and then add the value they place on the benefits, harms and conveniences in order to make a decision – a complex process that cannot be completed accurately without written information.

A patient decision aid is a tool meant to provide accurate information regarding a health condition, detailing the options available and the associated harm, benefit and risk, to increase patient knowledge and assist them in making an informed decision¹⁰. A recent systematic review on patient decision aids concluded that patient decision aids help patients be comfortable and confident with the decision they are making and limited evidence suggests they may improve certain health outcomes such as quality of life and reduced anxiety¹¹.

The objective of this project was to develop and validate a patient decision aid to assist patients in choosing between different anticoagulation treatment options for atrial fibrillation. To do this well, though, requires first an understanding of atrial fibrillation, then clarity on what stroke or major bleeding would feel like and its effect on prognosis. The decision aid then presents information on the different treatment options namely, no treatment, aspirin, warfarin, dabigatran, rivaroxaban and apixaban. The validation assessed decisional conflict, change in a knowledge test before and after the decision aid, and overall clarity, comprehensiveness and helpfulness in making evidence-informed decisions.

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Methodology

Participants – A convenience sampling strategy was used to recruit patients from a cardiology and a thrombosis clinic as well as inpatient wards in Hamilton, Ontario. Eligible patients had to be 60 years or older in order to be representative of the population considered for anticoagulation. Patients had to read and understand English and demonstrate adequate cognition as assessed by a validated orientation-memory-concentration test¹².

Study Design – Prospective case series assessing face validity and construct validity.

Development of Decision Aid – A literature search was conducted using MEDLINE, original Phase 3 trial reports of each NOAC, publicly available Health Canada and FDA reviews, and a Canadian indirect meta-analysis of comparative effectiveness, safety and cost-effectiveness of NOACs versus warfarin^{1,13-16}. The decision aid was revised from previous decision aids for decisions regarding warfarin, which included general information on AF, stroke, bleeding and the benefits and harms and practicalities of use of warfarin¹⁷⁻¹⁹. After a series of meetings with stroke neurologists, cardiologists, hematologists, drug safety experts, epidemiologists and statisticians, we updated all descriptions, rates and developed a series of charts portraying all important outcomes for comparisons between 1) no treatment, aspirin and anticoagulants, 2) warfarin and NOACs, and 3) dabigatran, rivaroxaban and apixaban^{1,13-16,20-25}. This was followed by an evaluation of the decision aid with International Patient Decision Aid Standards (IPDAS) standard criteria²⁶. Finally, prototypes were reviewed with patients, an iterative process that led to more refinement of the decision aid.

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Interview Process - Study participants who signed informed consent first received a standardized orientation to the project and were screened for cognitive impairment through a validated orientation-memory-concentration test¹². They then completed a short baseline knowledge test about atrial fibrillation, outcomes and anticoagulants. After proceeding through the decision aid booklet, they made a treatment choice and answered a short group of questions regarding their decisional conflict, knowledge of atrial fibrillation and anticoagulants, assessment of clarity and comprehensiveness of the information presented and overall helpfulness of the decision aid.

Outcomes – The primary outcome tested was confidence in making decisions regarding their treatment, using a validated decisional conflict scale. The secondary outcomes included: the change in knowledge scores and ratings of clarity, helpfulness and comprehensiveness.

Analysis – Descriptive summary measures were used to summarize patient demographics. Results of the decisional conflict scale were scored and interpreted according to the user manual. A student paired t-test was used to compare pre and post knowledge scores.

Results

A total of 41 patients (mean age 74.9 [SD 8.7], 29.3% female) participated in this interim report on our study. The baseline characteristics are outlined in Table 1.

Decisional Conflict

After using the patient decision aid, the mean total decisional conflict score was 4.3 (SD 7.1). The decisional conflict score ranges from 0 to 100, with 0 being “feels extremely certain about

the best choice” and 100 being “feels extremely uncertain about the best choice”. In this study, a score of 4.3 indicates that overall patients felt very certain about and comfortable with the anticoagulant choice they made.

Atrial Fibrillation Knowledge

The mean knowledge score before giving the decision aid was 7.7 (SD 1.4) out of a total score of 10. After the implementation of the decision aid, the mean knowledge score of the participants was 9.4 (SD 0.8). This difference in mean knowledge scores between pre- and post-decision aid was statistically significant ($p < 0.001$). These results show an improvement in knowledge of AF and anticoagulants after going through the patient decision aid.

Helpfulness, Clarity and Comprehensiveness

Overall, the participants found the decision aid would be helpful in making a decision about their anticoagulant treatment for AF. On a scale of 1 to 7 with 1 being not helpful and 7 being very helpful, the mean score of the participants was 6.42. The presented information on atrial fibrillation, stroke, bleeding, benefits and harms of the anticoagulant choices, and the summary comparison charts were rated as good or excellent in terms of clarity and comprehensiveness (See Table 2 for the ratings of each section of the decision aid). Only one participant (2.6%) found the presented information in the decision aid difficult to understand.

Table 1: Baseline Patient Characteristics

Characteristic (number (%) unless otherwise stated)	Participants (N=41)
Mean Age – years (SD)	74.9 (8.7)
Female sex	12 (29.3)
Education Level	
Elementary school only	7 (17.1)
Secondary school only	15 (36.6)
College or university only	17 (41.5)
Post-graduate education	2 (4.9)
Taken anticoagulants in past or currently	36 (87.8)
Not on anticoagulants currently	5 (12.2)
Currently taking an anti-platelet drug or NSAID	12 (29.3)
Number of Prescription Medications	
0 prescription medicines	0 (0)
1-4 prescription medicines	5 (12.2)
5-6 prescription medicines	18 (43.9)
≥7 prescription medicines	18 (43.9)
Medical History (from patient only)	
Atrial fibrillation	38 (92.7)
Artificial heart valves	4 (9.8)
Prior Stroke or Transient Ischemic Attack	6 (14.6)
Myocardial infarction	8 (19.5)
Angina	4 (9.8)
Previous stents	5 (12.2)
Coronary artery bypass graft (CABG)	3 (7.3)
Congestive heart failure	6 (14.6)
Hypertension	30 (73.2)
Diabetes	3 (7.3)
Peripheral artery disease	2 (4.9)
Poor kidney function	0 (0)
Poor liver function	0 (0)
Cancer	12 (29.3)
CHA₂DS₂-VASc score	
Mean	3.3 ± 1.4
Distribution – no. (%)	
0	0 (0)
1	4 (9.8)
≥2	37 (90.2)
HAS-BLED score	
Mean	2.1 ± 0.9
Distribution – no. (%)	
0	1 (2.4)
1-2	29 (70.7)
≥3	11 (26.8)

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Table 2: Study Outcomes

Cognition Screen Test	Mean score (SD)
OMCT score	1.4 (1.3)
Decisional Conflict Scores	Mean score (SD)
Informed subscale	4.3 (11.5)
Values Clarity subscale	6.4 (15.3)
Support subscale	3.7 (8.5)
Uncertainty subscale	3.0 (10.0)
Total score	4.3 (7.1)
Knowledge Scores	Mean score (SD)
Pre-decision aid score	7.7 (1.4)
Post-decision aid score	9.4 (0.8)
Ratings of the way information is presented	Mean score (SD) <i>Poor=1, Fair=2, Good=3, Excellent=4</i>
Atrial Fibrillation	3.4 (0.6)
Description of Stroke	3.5 (0.6)
Description of Bleeding	3.6 (0.5)
Benefits of Treatment Choices	3.5 (0.6)
Harms of Treatment Choices	3.4 (0.6)
Summary Comparison Charts	3.6 (0.6)

Limitations

The main limitation of this report is the incomplete sample size. Our target sample size is 80 patients but we have reached only halfway in our patient recruitment. Secondly, the patient decision aid was designed to help patients with atrial fibrillation who need information to make an informed decision with their physician, especially those deciding whether to start anticoagulation. The majority of the patients in this study were already on anticoagulants. This was due to short timeframe for the study, lack of sufficient funding, and the difficulty in recruiting patients at the specific time of considering starting anticoagulant therapy. The type of

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information obtained from the clinical trials was another minor limitation. For example, all of the large pivotal randomized trials on NOACS compared each NOAC separately to warfarin. No study compared each NOAC to another. Similarly, precise estimates of outcomes for no therapy or for aspirin therapy in the modern age where warfarin and NOACs are used frequently, were difficult to obtain.

Recommendations

Our immediate task is to complete the validation study to its desired sample size of at least 80 participants. Then it is imperative to test the use of the decision aid in a randomized trial to see if use improves decision making, improves adherence once a shared decision is made, and improves clinical outcomes. One very intriguing aspect of decision aids is the potential for physicians and patients to disagree on a course of action after reviewing the same information. We and others have found that patients are less likely to choose anticoagulation than physicians would wish them to, based on the same evidence^{17,27-28}. In addition, this project will be used to inform a larger initiative, just organizing, to put together an electronic anticoagulant management decision support system that physicians, pharmacists, patients and caregivers will be able to access via a personal health record or teletriage system. The findings of this study, once complete, will be disseminated through publications in medical journals and poster presentations at conferences and rounds. We will be ensuring that overall results are available in the clinics where patients were recruited. A grant application is being prepared for the upcoming CPSI competition that will incorporate some of this research.

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Student Learning

I had the opportunity to work on this research study from the very beginning as part of my graduate training in the Health Research Methodology program at McMaster University. During the process, I learned many of the important skills needed in research. From preparing a submission to the Ethics Research Board and applying to grants, I learned the amount of preliminary work that is required when starting a study. Researching measurement tools and different aspects of my research study was fundamental in ensuring that I was using the best possible evidence to back up my project. Many times I had to compare and contrast different tools and critique various studies to evaluate the best tool to use. This process helped me hone my skills in critical appraisal of literature. Data gathering was another important skill I began developing as I started interviewing patients. This practical application was an important step in making me aware of what research entails. Presenting at conferences and research rounds taught me the importance of being concise in my explanations and helped me develop skills in communication. Lastly, this project has taught me many skills related to project management such as time management, working in a team, communicating with supervisors, and the importance of collaboration.

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Appendices

N/A

Presentations

- 1) Slide show presentation at Clinical Pharmacology & Toxicology rounds at St. Joseph's Hospital, Hamilton, Ontario (available upon request)
- 2) Presented research poster at 2014 CSEB National Student Conference (available upon request)

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