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A Patient Decision Aid Regarding Antithrombotic Therapy for Stroke Prevention in Atrial Fibrillation

A Randomized Controlled Trial

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DECISION AIDS ARE TOOLS designed to help patients participate in the clinical decision-making process and make informed choices consistent with their personal values. Compared with general educational materials (such as informational pamphlets), decision aids provide detailed descriptions of clinically important outcomes and their consequences, provide quantitative information about the likelihood of these outcomes (often tailored to the patient's own clinical risk profile), are more explicit about the therapeutic choices, and encourage patients to indicate which therapy they currently favor.¹ Decision aids are usually developed for clinical situations in which the relative values of the benefits vs risks are unclear. They are designed to be adjuncts to the patient-physician interaction rather than substitutes. A number of formats for decision aids are available, including interactive video-

Context Decision aids are tools designed to help patients participate in the clinical decision-making process.

Objective To determine whether use of an audiobooklet (AB) decision aid explaining the results of a clinical trial affected the decision-making process of study participants.

Design Randomized controlled trial conducted from May 1997 to April 1998.

Setting Fourteen centers that participated in the Stroke Prevention in Atrial Fibrillation (SPAF) III trial.

Participants A total of 287 patients from the SPAF III aspirin cohort study, in which patients with atrial fibrillation and a relatively low risk of stroke received 325 mg/d of aspirin and were followed up for a mean of 2 years.

Intervention At the end of SPAF III, participants were randomized to be informed of the study results with usual care plus use of an AB (AB group) vs usual care alone (control group). The AB included pertinent information to help patients decide whether to continue taking aspirin or switch to warfarin.

Main Outcome Measures Patients' ability to make choices regarding antithrombotic therapy, and 6-month adherence to these decisions. Their knowledge, expectations, decisional conflict (the amount of uncertainty about the course of action to take), and satisfaction with the decision-making process were also measured.

Results More patients in the AB group made a choice about antithrombotic therapy than in the control group (99% vs 94%; $P = .02$). Patients in the AB group were more knowledgeable and had more realistic expectations about the risk of stroke and hemorrhage (in the AB group, 53%-80% correctly estimated different risks; in the control group, 16%-28% gave correct estimates). Decisional conflict and satisfaction were similar for the 2 groups. After 6 months, a similar percentage of patients were still taking their initial choice of antithrombotic therapy (95% vs 93%; $P = .44$).

Conclusions For patients with atrial fibrillation who had participated in a major clinical trial, the use of an AB decision aid improved their understanding of the benefits and risks associated with different treatment options and helped them make definitive choices about which therapy to take. Further studies are necessary to evaluate the acceptability and impact of decision aids in other clinical settings.

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For editorial comment see p 779.

discs,² audiobooklets (ABs),³ and decision boards.⁴

Patients with atrial fibrillation have an increased risk of stroke, and antithrombotic therapy is widely recommended for stroke prevention.⁵ Long-term therapy with warfarin decreases the risk of stroke by about 68%,⁶ and aspirin decreases the risk by 21%.⁷ However, use of warfarin is associated with a greater chance of major bleeding⁸ and is more complicated to use than aspirin.⁹ Since individual patients with atrial fibrillation are likely to perceive differently the trade-off between the efficacy and adverse effects of warfarin vs aspirin therapy, there is no right or wrong choice of antithrombotic therapy for many of these patients. Thus, a decision aid may be beneficial.

To test the validity of a previously developed risk stratification scheme, the Stroke Prevention in Atrial Fibrilla-

tion (SPAF) investigators recently completed a trial (SPAF III) in which patients with atrial fibrillation who were deemed to be at relatively low risk of stroke were treated with 325 mg/d of aspirin and followed up for a mean of 2 years.^{10,11} At the end, participants were informed of the study results and, in conjunction with their physicians, used this information to decide whether they wished to continue taking aspirin or switch to warfarin therapy. To assess the effect of a decision aid on the decision-making process, they were randomized to receive or not receive an AB in addition to usual counseling.

METHODS

All 20 SPAF centers were invited to participate in the randomized trial. All patients in participating centers who were in the SPAF III aspirin cohort study¹⁰ were eligible for this study, except those

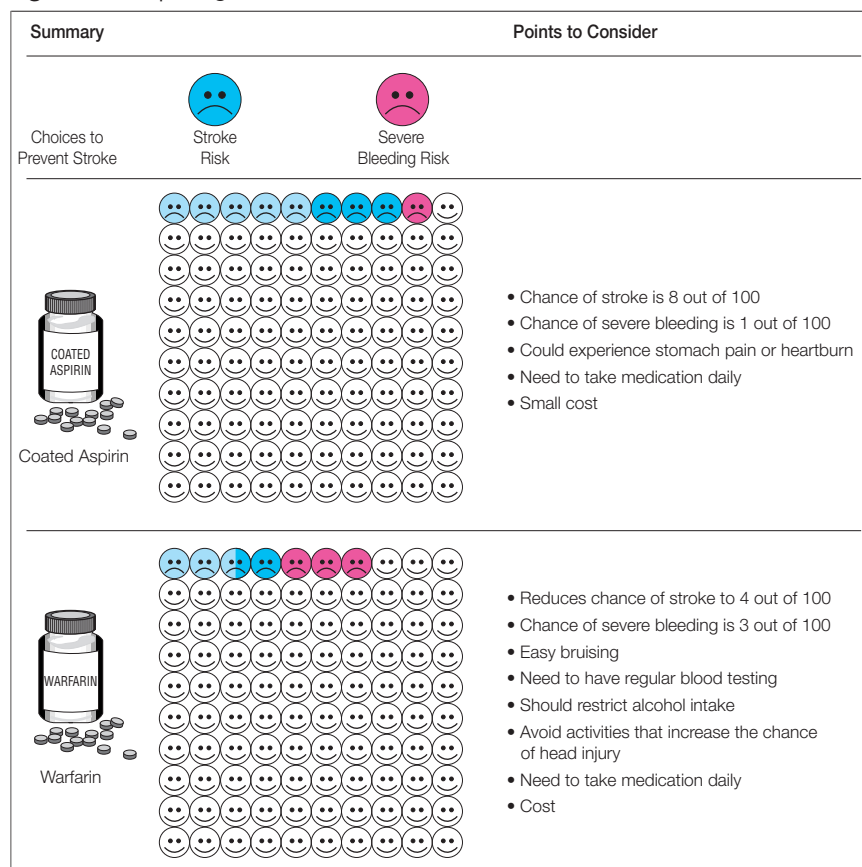
who had high-risk criteria or had a major hemorrhage during the study. The ethics review boards of each participating center approved the study, and informed consent was obtained from all participants. Pertinent patient characteristics (eg, age, sex, educational level, and previous use of warfarin and aspirin) were collected at entry into SPAF III.

According to a computer-generated scheme, administered from a central location to block the sequence from pre-viewing, patients were randomized to receive the AB or usual care. Randomization was also stratified by center and the presence of a history of hypertension.

Decision Aid Group

The AB decision aid consisted of a 29-page booklet, a personal worksheet, and a 20-minute audiotape that guided the participants through the booklet and worksheet. The booklet highlighted key points (similar to a slide presentation), and the audiotape connected the points in a narrative format, providing more detail than the booklet. The AB contained descriptions of the consequences of a minor stroke, a major stroke, and a major hemorrhage; the blood monitoring required for warfarin therapy; and the 2-year probabilities of stroke and major hemorrhage for patients taking aspirin or warfarin. Probabilities were presented in the booklet using 100 icons (FIGURE 1), whereas the text and AB also presented the chance of experiencing and not experiencing a stroke in percentages. The probability of a stroke while taking aspirin was derived directly from the results of the SPAF III cohort study¹⁰ in which the patients had recently participated (3% over 2 years in patients without a history of hypertension and 8% in patients with a history of hypertension). The probability of stroke while taking warfarin was calculated by assuming that warfarin was approximately 50% more efficacious than aspirin (2% over 2 years for patients without a history of hypertension and 4% for patients with a history of hypertension).⁶ The risk of major hemorrhage was presented as 1% over 2

Figure 1. Example Page From Audiobooklet



Light blue indicates minor stroke; dark blue, major stroke. Smiling faces indicate no stroke or major bleeding.

years while taking aspirin and 3% while taking warfarin.⁶ An accompanying 12-page physician's manual was also developed, which summarized the material in the AB and provided references.

After reviewing the booklet, patients completed a 1-page worksheet. It included sections that clarified their values for possible outcomes (eg, stroke and major bleeding), asked them to list any questions they had about the decision, and elicited which therapy (aspirin, warfarin, or unsure) they were inclined to take. Participants also indicated their preferred role in the decision-making process (ie, their physician should make the decision, the patient should make the decision, or the decision should be shared).

The AB was provided as an adjunct to each center's usual decision-making process at the end of the trial. Patients randomized to receive the decision aid were sent the AB a few days before they met with their physicians. They reviewed the AB and completed the personal worksheet before their visits with their physicians. The physicians received copies of the physician's manual before they met the patients.

Control Group

Control group subjects received usual care, ie, no change was made to the usual manner in which each center communicated the results of the SPAF III study to patients or to the way in which the decision regarding type of antithrombotic therapy was made. The methods used by centers to inform participants about the results of SPAF III varied. Of the participating centers, 7 asked participants to return to the SPAF clinic to discuss the results of the study, 5 sent summaries of the results of the study to the patients' personal physicians and asked patients to arrange appointments with these physicians, and 2 held an end-of-study gathering at which participants were given the study results and asked to follow up with their personal physicians.

Outcome Measures

One to 4 days after meeting with their physicians, all patients completed a ques-

tionnaire eliciting information about the following outcome measures.

Patient Choices. Patients were asked to indicate whether a decision regarding the choice of antithrombotic therapy had been made in conjunction with their physician and, if so, what this choice was. On a 5-point Likert scale, they also judged the relative strength of their personal input into the choice vs their physicians'.

Knowledge. Knowledge was tested using 23 questions about atrial fibrillation, stroke, and the advantages and disadvantages of taking warfarin or aspirin. These questions (eg, "Taking aspirin daily means that you have to go for regular blood testing") had the potential responses "true," "false," and "unsure."

Expectations. Patients' expectations about the probability of stroke and major hemorrhage with aspirin or warfarin therapy were quantitatively assessed with 4 questions. Each question contained 14 response options on a probability scale (eg, "If you continue to take aspirin, your risk of stroke during the next two years is. . . ." Response options ranged from "0% to 0.5%" to "80% to 100%").

Decisional Conflict. The decisional conflict scale¹² measured patients' uncertainty about which therapy to choose, modifiable factors contributing to uncertainty (believing themselves to be uninformed, unclear about values, and unsupported in decision making), and perceived effective decision making. The scale is reliable,^{12,13} discriminates between those who make or delay decisions,^{12,13} is responsive to change,^{3,14,15} and discriminates between different decision-supporting interventions.^{3,16,17} Two items were added to elicit patients' perceptions that they were informed about the benefits and risks of warfarin and, separately, about benefits and risks of aspirin. This did not affect the scale's reliability in this study (Cronbach α = .92).

Satisfaction. Satisfaction with various aspects of the decision-making process was assessed with 6 questions using a 5-point Likert scale (1, strongly agree; 2, agree; 3, neither agree nor disagree; 4, disagree; and 5, strongly disagree).

Six-Month Adherence. Adherence to their decisions regarding antithrombotic therapy was assessed 6 months later using a brief questionnaire administered by telephone. Participants were asked which therapy they were currently taking and the reasons for any change from their original decision.

Copies of the study materials are available on the Internet (<http://www.lri.ca>).

Analysis

A sample size calculation was not performed because we attempted to enroll as many patients from the SPAF III aspirin study as possible. Differences in outcomes between the patients who received the AB and those in the control group were compared with χ^2 and t tests as appropriate. A forward stepwise logistic regression procedure was performed to adjust raw outcome proportions using significant covariates to predict outcomes. Covariates were submitted to the logistic model at $P < .10$. A priori, the baseline factors thought most likely to affect the impact of the decision aid, and, thus, included in the model, were age, sex, education, and whether patients had ever taken warfarin prior to participation in SPAF III. An α level of .05 was used to indicate statistical significance.

RESULTS

The trial was conducted from May 1997 to April 1998. Two hundred eighty-seven patients at 14 SPAF centers were randomized to either receive ($n = 139$) or not receive ($n = 148$) the AB. FIGURE 2 shows participant flow through the trial. TABLE 1 compares characteristics of SPAF III patients who did and did not participate in the AB trial. The mean (SD) length of clinic visits did not differ significantly between the AB and control groups (AB group, 27 [18] minutes; control group, 25 [15] minutes; $P = .51$).

Patient Choices

A few days after visits with their clinicians, more patients in the AB group ($n = 138$) were able to make definite choices regarding antithrombotic therapy compared with those in the con-

trol group ($n = 139$; 99% vs 94%; $P = .02$). Overall, the proportion of patients who decided to take warfarin was higher in the control group ($n = 12$ [8%] in the AB group, $n = 17$ [11%] in control group; $P = .02$). The 119 patients with hypertension ($n = 20$ [17%] overall; 7 [12%] of 58 in AB group, 13 [21%]

of 61 in control group) were more likely to choose warfarin compared with the 168 patients without hypertension (9 [5%] overall; 5 [6%] of 81 in AB group, 4 [5%] of 87 in control group) ($P = .003$). Patients taking long-term warfarin therapy prior to enrollment were more likely to switch to warfarin than those who were not (10 [13%] of 75 vs 15 [7%] of 212, respectively; $P = .05$).

Eighty-seven (63%) worksheets from the 139 patients in the AB group were returned. After review of the AB, 79 (91%) of the 87 patients were inclined to take aspirin, 1 (1%) to take warfarin, and 7 (8%) were unsure. After meeting with their practitioners, all patients who indicated a preference except 2 decided to take the medication they were favorably disposed toward (those 2 decided to take warfarin). Of the patients who were unsure, 6 decided to take aspirin and 1 decided to take warfarin.

Similar percentages of participants in the AB and control groups reported that they, rather than their physicians, made the decision regarding antithrombotic therapy ($n = 85$ [61%], AB group; $n = 83$ [56%], control; $P = .43$). Participants' choice of antithrombotic therapy (aspirin or warfarin) was not affected by the method with which centers informed participants of the results of the SPAF III aspirin study (ie, clinic visit, letter to personal physician, end-of-study gathering) ($P = .62$).

Knowledge and Expectations

Patients who reviewed the AB were generally more knowledgeable about the pertinent clinical issues regarding stroke, atrial fibrillation, and their treatment and consequences compared with patients who received usual care (TABLE 2). Patients receiving the AB were also more willing than those in the control group to make quantitative estimates of their chance of stroke and major bleeding when taking aspirin or warfarin (134 [96%] of 139 vs 113 [76%] of 148, respectively; $P < .001$). Compared with patients receiving usual care, a higher percentage of patients reviewing the AB gave correct quantitative estimates of their stroke and bleeding risks when taking aspirin or warfarin (Table 2). As an example, individual responses of participants with hypertension regarding their chance of stroke if taking warfarin are shown in FIGURE 3.

Patient Decisional Conflict

There was no statistically significant difference in overall decisional conflict between patients who received the AB and those who did not ($P = .14$) (TABLE 3). When examining subscales of the decisional conflict scale, those receiving the AB believed they were more informed compared with those who did not (-0.21 units; 95% confidence interval [CI], -0.34 , to -0.08).

Figure 2. Flow of Study Participants

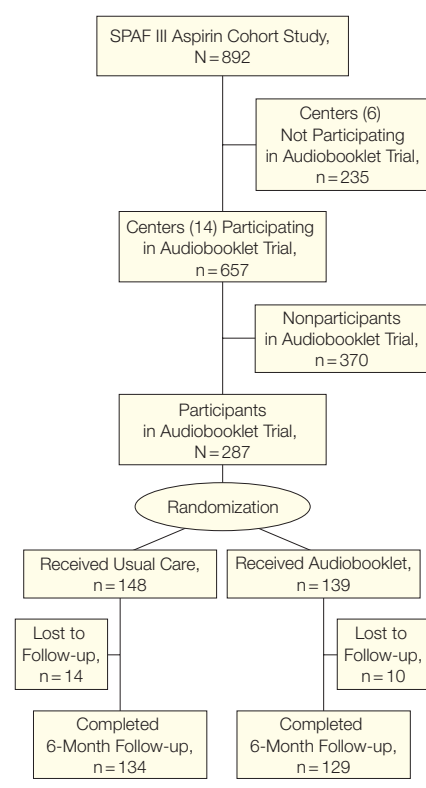


Table 1. Participant Characteristics at Time of Entry Into SPAF III*

| | Participants in AB Trial (n = 287) | | AB Trial Nonparticipants at Sites Participating in AB Trial (n = 370) | SPAF III Aspirin Study Participants at Sites Not Participating in AB Trial (n = 235) | All SPAF III Aspirin Study Participants (N = 892) |
|--|---------------------------------------|-------------------------|---|---|--|
| | AB (n = 139) | Usual Care (n = 148) | | | |
| Mean age, y | 65 | 67 | 69 | 66 | 67 |
| Sex, % female | 24 | 24 | 20 | 22 | 22 |
| Education (high school or greater), % | 90 | 91 | 82 | 84 | 85 |
| Mean No. of medications | 2.9 | 3.0 | 3.5 | 2.8 | 3.1 |
| Mean MMSE score (out of 35) | 32 | 32 | 32 | 32 | 32 |
| Taking aspirin, %† | 60 | 63 | 67 | 67 | 63 |
| Ever taken warfarin, %† | 37 | 38 | 33 | 31 | 33 |
| Reported their physician should play important role in decision-making process, % | 80 | 81 | Not available | Not available | Not available |

*SPAF indicates Stroke Prevention in Atrial Fibrillation trial; AB, audiobooklet; and MMSE, Mini-Mental State Examination.

†Prior to enrollment in SPAF III.

Table 2. Patient Knowledge and Expectations

| Correct Responses, % (No. Correct/Total Answered) | | | | | | |
|---|--|------------------------|--|-------------------------|--|---------------------|
| AB Decision Aid (n = 139) | | | | Usual Care (n = 148) | | Difference (95% CI) |
| | | | | | | |
| Knowledge questions | | | | | | |
| Atrial fibrillation– and stroke–related (6 questions) | | 93.4 (779/834) | | 90.2 (801/888) | | 3.2 (–4.5 to 10.9) |
| Aspirin-related (9 questions) | | 68.3 (854/1251) | | 52.4 (698/1332) | | 15.9 (4.6 to 27.2)‡ |
| Warfarin-related (9 questions) | | 78.4 (981/1251) | | 63.5 (846/1332) | | 14.9 (4.6 to 25.2)‡ |
| | | | | | | |
| Hypertension (No.) | | | | | | |
| AB (n = 58) | | Usual Care (n = 61) | | Difference (95% CI) | | |
| | | | | | | |
| AB (n = 81) | | Usual Care (n = 87) | | Difference (95% CI) | | |
| | | | | | | |
| Estimates of outcome probabilities† | | | | | | |
| Unwilling to give estimate | | 3 (2) | | 26 (16) | | –23 (–35 to –11) |
| Chance of stroke when: | | 59 (34) | | 24 (15) | | 35 (19 to 51) |
| Taking aspirin | | 59 (34) | | 28 (17) | | 31 (13 to 49) |
| Taking warfarin | | 55 (32) | | 26 (23) | | 43 (29 to 57)‡ |
| Chance of bleeding when: | | 53 (31) | | 21 (13) | | 32 (15 to 49) |
| Taking aspirin | | 55 (32) | | 26 (23) | | 43 (29 to 57)‡ |
| Taking warfarin | | 53 (31) | | 16 (14) | | 48 (35 to 61)‡ |

*AB indicates audiobooklet; CI, confidence interval.

†Patients must choose correct response on 14-point probability scale.

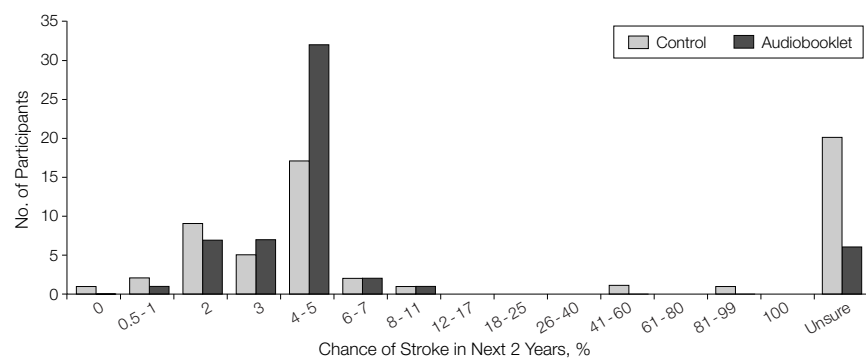
‡ $P < .001$.

Patient Satisfaction

Use of the AB did not significantly affect patients' satisfaction with various aspects of their interaction with their practitioner (TABLE 4), although there was a trend toward patients using the AB to become more satisfied with the decision-making process ($P = .10$).

Patient Adherence

Six-month follow-up data regarding adherence to patients' initial choice of therapy were available for 92% (263/287) of the participants. A similar percentage of patients in both groups continued to take the therapy that was initially chosen (AB group, 123 [95%] of 129; control group, 125 [93%] of 134; $P = .44$). For patients who initially chose warfarin, 2 (17%) of 12 in the AB group switched to aspirin 6 months later, while 1 (6%) of 17 in the control group switched. For those who initially chose aspirin, 110 (96%) of 114 in the AB group continued taking aspirin, with 4 (3%) switching to warfarin; for the control group, 104 (93%) of 112 continued taking aspirin with 8 (7%) switching to warfarin. All patients who were undecided about their choice of antithrombotic therapy immediately after their clinic visit ($n = 8$) were taking aspirin 6 months later.

Figure 3. Participants' Expectations Regarding Chance of Stroke

Participants' expectations regarding chance of stroke in the next 2 years if taking warfarin (hypertensive group). The correct answer is 4% to 5%.

Effect of Baseline Factors on Outcomes

While controlling for use of the AB, stepwise logistic regression revealed that certain baseline factors were independent predictors of the various study outcomes. Previous warfarin use (odds ratio [OR], 2.18; 95% CI, 1.01-4.74; $P = .04$) was an independent predictor of choosing warfarin as the initial antithrombotic therapy. Age categories were defined as younger than 60 years, 60 to 75, and older than 75 years. Younger age (OR, 1.49; 95% CI, 1.03-2.15; $P = .04$) and male sex (OR, 1.89; 95% CI, 1.07-

3.33; $P = .04$) were independent predictors of lower overall decisional conflict score. Higher educational level, defined as did not complete high school, did complete high school, or greater (OR, 1.96; 95% CI, 1.33-2.89; $P = .01$) and younger age (OR, 1.67; 95% CI, 1.14-2.45; $P = .04$) were significantly associated with higher knowledge scores. No baseline factor was independently associated with improved satisfaction scores.

COMMENT

Compared with patients in the usual care group, those who used the deci-

sion aid were more likely to make a decision regarding antithrombotic therapy; were more knowledgeable about treatment options, benefits, and risks; and had much more realistic expectations about their chance of stroke and major bleeding. However, they did not demonstrate significant differ-

ences in overall decisional conflict or in satisfaction with the decision-making process.

The results of this trial are compatible with other randomized controlled trials involving patients faced with treatment decisions about hormone replacement therapy,³ benign prostatic hyper-

plasia,² and coronary artery disease.¹⁶ In these trials, compared with patients receiving usual care, patients using decision aids were consistently more knowledgeable, believed they were more informed about the pertinent clinical issues, and had more realistic expectations about the probability of outcomes. Also, another study did find a positive effect on satisfaction for patients contemplating surgery for benign prostatic hyperplasia.²

Use of the AB did exert a small influence on the eventual choice of antithrombotic therapy. With greater knowledge and awareness of pertinent clinical issues, slightly more patients who used the AB compared with control patients preferred to continue taking aspirin rather than to switch to warfarin. This result is supported by results of other trials that evaluated the impact of decision aids. In those trials,^{2,16} patients made more conservative decisions regarding therapy after being informed of the benefits and risks of therapeutic options, resulting in trends toward lower rates of surgery for benign prostatic hyperplasia² and coronary artery disease,¹⁶ respectively. The conservative selection may be due to more realistic expectations of potential benefits and harms and to correction of exaggerated notions of the baseline risks and benefits of treatment after exposure to the decision aids.

By participating in the SPAF III aspirin trial, all patients were familiar with taking aspirin daily, whereas only 38% had taken warfarin previously. Therefore, given the explicit description of the risks and inconveniences of aspirin and warfarin therapy in the AB, it was not surprising that those reviewing the AB demonstrated greater knowledge and awareness of issues regarding warfarin therapy. More surprisingly, patients receiving the AB, compared with patients receiving usual care, also demonstrated significantly greater knowledge and awareness of issues regarding aspirin therapy.

A similar percentage of patients in the AB and control groups believed that their physicians played an important role in the decision-making process,

Table 3. Levels of Decisional Conflict

| | Audiobooklet (n = 139) | Usual Care (n = 148) | Difference (95% CI)* |
|--|---------------------------|-------------------------|------------------------|
| Total Decisional Conflict Scale (DCS) score, mean (SD)†‡ | 1.65 (0.45) | 1.74 (0.54) | |
| Subscales, mean (SD)† | | | |
| Uncertainty | 1.84 (0.84) | 1.79 (0.76) | 0.05 (−0.13 to 0.23) |
| Uninformed§ | 1.63 (0.53) | 1.84 (0.59) | −0.21 (−0.34 to −0.08) |
| Unclear values | 1.65 (0.50) | 1.76 (0.59) | −0.11 (−0.22 to 0.00) |
| Unsupported | 1.65 (0.52) | 1.66 (0.56) | −0.01 (−0.11 to 0.09) |
| Ineffective choice | 1.54 (0.52) | 1.62 (0.59) | −0.08 (−0.20 to 0.04) |
| Expressing no problems with each DCS item (score ≤2), % | | | |
| Easy choice | 87.8 | 90.5 | −2.7 (−10.0 to 4.6) |
| Sure what to do | 87.7 | 85.0 | 2.7 (−5.2 to 10.6) |
| Clear best choice | 86.3 | 89.2 | −2.9 (−10.5 to 4.7) |
| Know alternatives | 100.0 | 95.3 | 4.7 |
| Know benefits of aspirin | 99.3 | 98.0 | 1.3 |
| Know benefits of warfarin§ | 85.6 | 69.2 | 16.4 (6.6 to 26.2) |
| Know risks of aspirin | 97.8 | 93.9 | 3.9 |
| Know risks of warfarin§ | 89.2 | 80.1 | 9.1 (0.7 to 17.5) |
| Aware of personal importance of: | | | |
| Stroke reduction | 97.1 | 95.3 | 1.8 |
| Benefits and risks of aspirin | 97.1 | 88.5 | 8.6 |
| Benefits and risks of warfarin§ | 91.4 | 82.7 | 8.7 (1.4 to 17.4) |
| Feel no pressure from others | 96.4 | 97.3 | −0.9 |
| Have enough support | 84.9 | 89.8 | −4.9 (−12.6 to 2.8) |
| Have enough advice | 93.6 | 91.9 | 1.7 (−4.4 to 7.7) |
| Informed choice | 98.6 | 94.6 | 4.0 |
| Reflects values | 94.9 | 93.2 | 1.7 (−3.8 to 7.2) |
| Will adhere to decision | 89.9 | 91.9 | −2.0 (−8.7 to 4.7) |
| Satisfied with decision | 96.4 | 95.3 | 1.1 |

*For items with sufficient numbers in each cell (n>5) to allow calculation of 95% confidence intervals (CIs).

†Scale ranges from 1 (low decisional conflict) to 5 (high decisional conflict). Scores of 2.0 or lower are associated with implementing (rather than delaying) choices.

‡P = .14.

§P<.05.

Table 4. Participant Satisfaction

| | Audiobooklet (n = 139) | Usual Care (n = 148) | Difference (95% CI) |
|---|---------------------------|-------------------------|------------------------|
| Satisfaction with each item* (score ≤2) | | | |
| Physician helped me understand results | 87.8 | 85.1 | 2.7 (−5.3 to 0.7) |
| Physician understood what is important to me | 89.9 | 88.5 | 1.4 (−5.8 to 8.6) |
| Physician answered all questions | 90.7 | 91.9 | −1.2 (−7.7 to 5.3) |
| Satisfied with involvement in decision making | 98.6 | 96.0 | 2.6† |
| Satisfied with physician's involvement | 92.1 | 90.5 | 1.6 (−5.1 to 8.1) |
| Satisfied with process | 95.0 | 89.9 | 5.1 (−1.1 to 11.3) |

*Scale ranges from 1 (strongly agree) to 5 (strongly disagree).

†Insufficient numbers (n<5) to allow calculation of 95% confidence intervals (CIs).

showing that decision aids are supplements, rather than alternatives, to the patient-physician interaction.

Our study has several possible limitations. Contamination may have caused the limited effect of the decision aid for the outcomes of decisional conflict and 6-month adherence. During clinic visits with patients receiving usual care, physicians may have provided patients with information similar to that contained in the AB, making the benefit of the AB harder to detect. Randomizing participating centers might have reduced the possibility of contamination but would have increased the possibility of imbalance for pertinent participant characteristics between the AB and usual care groups.

Participants in the usual care group reported low overall decisional conflict and high satisfaction with the patient-practitioner interaction. Thus, there may have been a ceiling effect, with little chance of the AB significantly improving overall patient satisfaction with the decision-making process. Patients in this study may have been more likely to receive greater personalized care and been better informed about their conditions and treatment compared with average patients with atrial fibrillation, making the effects of the decision aid harder to detect. Therefore, the benefits of decision aids may be greater in usual care

settings. Further evaluation of our AB in a general clinic setting is needed.

Other possible limitations of our study include the relatively low percentage of eligible patients who participated. Also, some baseline characteristics (eg, socioeconomic status) that may have affected the influence of the AB were not included in our logistic regression analysis, because they were not recorded at SPAF III entry.

This study is the largest randomized trial of a decision aid; the patients were evaluated when they were making clinical decisions, and the outcome measures used were comprehensive. The decision aid was well accepted by patients, and those who received the AB were better informed about atrial fibrillation and the benefits and risks of the treatment alternatives than patients who received usual care. Previous studies have shown that many patients with atrial fibrillation are still not being prescribed warfarin therapy.^{18,19} In some circumstances, physicians may have inappropriately failed to offer warfarin therapy to high-risk patients (eg, patients with a previous transient ischemic attack). On the other hand, fully informed patients may have decided not to take warfarin because they perceived that the benefits did not outweigh the risks and inconvenience of therapy. Given the prevalence of atrial fibrillation in older persons, it would

seem appropriate to evaluate the acceptability and impact of decision aids for patients with atrial fibrillation in clinical practice. Decision aids should be tailored to the risk profile of individual patients, updated as new information becomes available, and evaluated for their effectiveness.

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REFERENCES

- Llewellyn-Thomas HA. Patients' health-care decision making. *Med Decis Making*. 1995;15:101-106.
- Barry MJ, Cherkin DC, Chang Y, Fowler FJ, Skates S. A randomized trial of a multimedia shared decision-making program for men facing a treatment decision for benign prostatic hypertrophy. *Dis Manage Clin Outcomes*. 1997;1:5-14.
- O'Connor AM, Tugwell P, Wells GA, et al. Randomized trial of a portable, self-administered decision aid for postmenopausal women considering long-term preventive hormone therapy. *Med Decis Making*. 1998;18:295-303.
- Levine MN, Gafni A, Markham B, MacFarlane D. A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. *Ann Intern Med*. 1992;117:53-58.
- Laupacis A, Albers G, Dalen J, Dunn MI, Jacobson AK, Singer DE. Antithrombotic therapy in atrial fibrillation. *Chest*. 1998;114(suppl 5):579S-589S.
- Atrial Fibrillation Investigators. Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation. [Published correction appears in *Arch Intern Med*. 1994;154:1449-1457.] *Arch Intern Med*. 1994;154:1449-1457.
- Atrial Fibrillation Investigators. The efficacy of aspirin in patients with atrial fibrillation. *Arch Intern Med*. 1997;157:1237-1240.
- Palareti G, Leali N, Coccheri S, et al, for the Italian Study on Complications of Oral Anticoagulant Therapy. Bleeding complications of oral anticoagulant treatment. *Lancet*. 1996;348:423-428.
- Gage BF, Cardinali AB, Owens DK. The effect of stroke and stroke prophylaxis with aspirin or warfarin on quality of life. *Arch Intern Med*. 1996;156:1829-1836.
- The SPAF III Writing Committee for the Stroke Prevention in Atrial Fibrillation Investigators. Patients with nonvalvular atrial fibrillation at low risk of stroke during treatment with aspirin. *JAMA*. 1998;279:1273-1277.
- Stroke Prevention in Atrial Fibrillation Investigators. Predictors of thromboembolism in atrial fibrillation. I. *Ann Intern Med*. 1992;116:1-5.
- O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making*. 1995;15:25-30.
- Bunn H, O'Connor A. Validation of client decision-making instruments in the context of psychiatry. *Can J Nurs Res*. 1996;28:13-27.
- Drake E, Engler-Todd L, O'Connor A, Hunter A. Evaluation of a decision aid for prenatal testing for women of advanced maternal age. *J Genet Counseling*. In press.
- Fiset V. *Evaluating the Effectiveness of a Decision Aid for Patients Considering Treatment Options for Stage-4 Non Small Cell Lung Cancer*. [master's thesis]. Ottawa, Ontario: University of Ottawa; 1998.
- Morgan MW. *A Randomized Trial of the Ischemic Heart Disease Shared Decision Making Program: An Evaluation of a Decision Aid*. [master's thesis]. Toronto, Ontario: University of Toronto; 1997.
- Rotherth ML, Holmes-Rovner M, Rovner D, et al. An educational intervention as decision support for menopausal women. *Res Nurs Health*. 1997;20:377-387.
- Albers GW, Yim JM, Belew KM, et al. Status of antithrombotic therapy for patients with atrial fibrillation in university hospitals. *Arch Intern Med*. 1996;156:2311-2316.
- Stafford RS, Singer DE. National patterns of warfarin use in atrial fibrillation. *Arch Intern Med*. 1996;156:2537-2541.