

Differences between perspectives of physicians and patients on anticoagulation in patients with atrial fibrillation: observational study

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Abstract

Objective To determine and compare physicians' and patients' thresholds for how much reduction in risk of stroke is necessary and how much risk of excess bleeding is acceptable with antithrombotic treatment in people with atrial fibrillation.

Design Prospective observational study.

Setting Tertiary and peripheral referral centres in Nova Scotia, Canada.

Participants 63 physicians who were treating patients with atrial fibrillation and 61 patients at high risk for atrial fibrillation.

Main outcome measures Participants underwent a face to face interview with a probability trade-off tool. Thresholds were determined for the minimum reduction in risk of stroke necessary and the maximum increase in risk of excess bleeding acceptable for treatment with aspirin and warfarin in people with atrial fibrillation.

Results The minimum number of strokes that needed to be prevented in 100 patients over two years for warfarin to be justified was significantly lower for patients than for physicians (1.8 (SD 1.9) *v* 2.5 (1.6), *P* = 0.009), whereas for aspirin there was no difference between patients and physicians (1.3 (1.3) *v* 1.6 (1.5), *P* = 0.29). The maximum number of excess bleeds acceptable in 100 patients over two years for use of warfarin and aspirin was significantly higher for patients than for physicians (warfarin 17.4 (7.1) *v* 10.3 (6.1); aspirin 14.7 (8.5) *v* 6.7 (6.2); *P* < 0.001 for both comparisons).

Conclusions Patients at high risk for atrial fibrillation placed more value on the avoidance of stroke and less value on the avoidance of bleeding than did physicians who treat patients with atrial fibrillation. The views of the individual patient should be considered when decisions are being made about antithrombotic treatment for people with atrial fibrillation.

Introduction

Atrial fibrillation is the most common chronic arrhythmia¹ and is a major risk factor for stroke.² Clinical trials have shown that warfarin³ and to a lesser extent

aspirin⁴ reduce the rate of stroke in patients with atrial fibrillation. Despite evidence of benefit, observational studies have consistently shown, for reasons that are not clear,⁵ an apparent underuse of antithrombotic drugs in these patients.^{6–10}

The decision to use antithrombotic drugs in patients with atrial fibrillation involves a consideration of the potential benefits versus the risks, inconveniences, and costs. We hypothesised that physicians and patients would differ in how they weigh these factors, which in turn would influence their decisions to prescribe or take antithrombotic drugs. We studied trade-offs in physicians and patients between risk of stroke and risk of bleeding when antithrombotic treatment is being considered.

Methods

Patients

We randomly selected patients who were at high risk of developing atrial fibrillation (that is, those with a previous diagnosis of congestive heart failure or myocardial infarction) from the database of the improving cardiovascular outcomes in Nova Scotia study (October 1997 to October 1998). The database comprised 1119 patients discharged with one of these diagnoses from hospital in Nova Scotia.¹¹

Exclusion criteria included: history of atrial fibrillation; current or previous use of warfarin; previous stroke; previous severe bleeding; no longer living in the province; could not be located; inability to participate due to illness; limited understanding of English; a score of less than 24 on the mini-mental state examination¹²; or failure of either eligibility scenario (see below). Patients with a history of aspirin use were not excluded as the use of aspirin is so ubiquitous in this patient population.

Physicians

We randomly selected family physicians and general internists or subspecialists from the physician registry of the Department of Health, Nova Scotia. Exclusion criteria included: not currently practising medicine; not having cared for a patient with atrial fibrillation in the preceding year; not located or moved out of the

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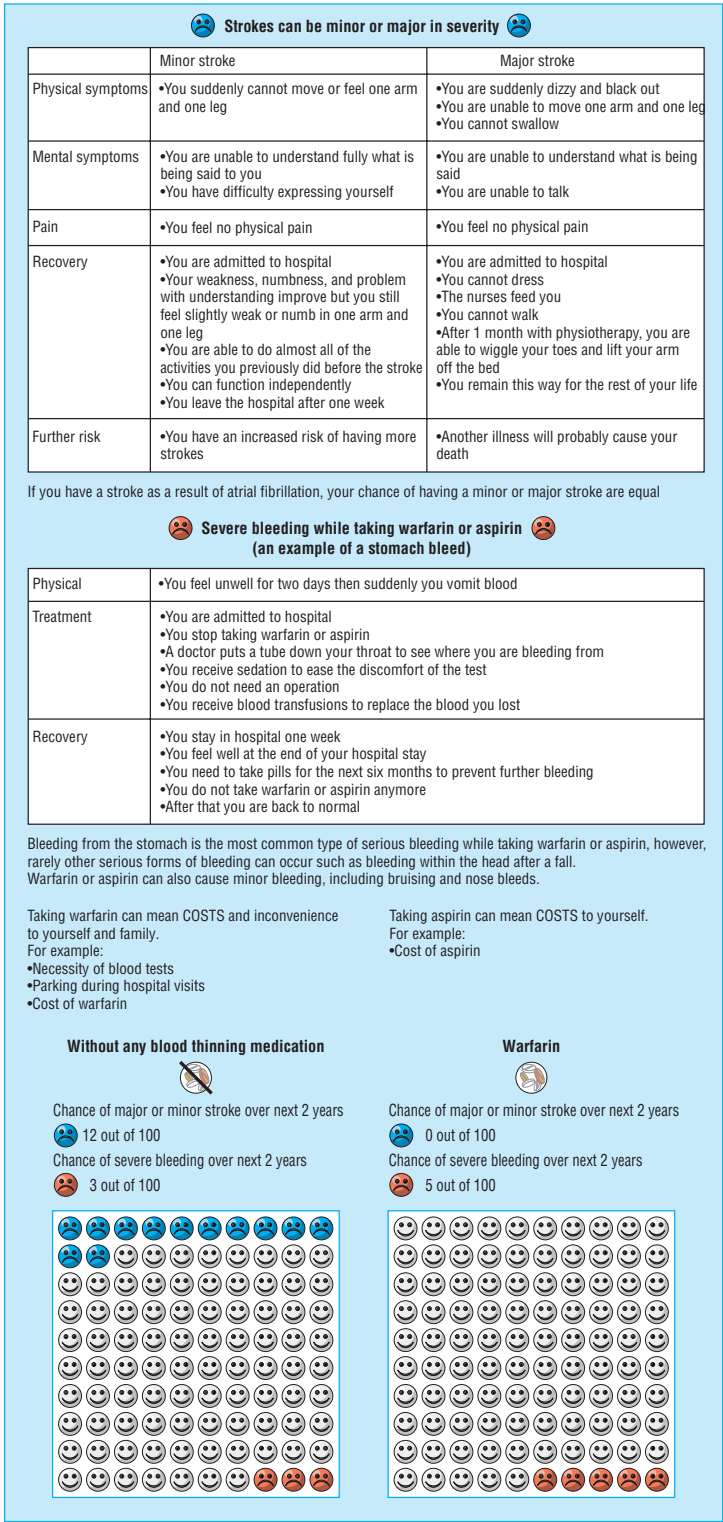


Fig 1 Example of pictorial flip charts

province; inability to participate due to illness; or failure of either eligibility scenario (see below).

Interview procedures

Participants underwent a structured face to face interview and information was presented both verbally and visually with the use of coloured pictorial flip charts (fig 1). The two people who interviewed the patients (BFB) and physicians (PJD) followed prewritten text during

the interview. Seven physicians and seven patients participated in a pilot interview to ensure understanding and consistency.

Baseline information

Participants read flip charts describing major and minor stroke, major and minor bleeding, and inconveniences and costs of treatments (fig 1). We told participants that the likelihood of a minor or major stroke was equal.³ We described the most common type of major bleed: a non-fatal gastrointestinal bleed.^{13 14}

Screening

Participants completed two eligibility scenarios that compared the outcomes of stroke and bleeding with no treatment and with a blood thinning treatment. The blood thinning medication decreased the risk of stroke and bleeding in the first scenario and did not affect the risk of stroke but increased the risk of bleeding in the second scenario. If participants did not select the blood thinning medication in the first scenario or selected it in the second scenario, they were excluded as we considered that their choice reflected inadequate comprehension.

Eliciting thresholds

Participants completed four clinical scenarios, the order of which was randomly assigned. Two scenarios (one for warfarin, one for aspirin) determined their thresholds for the minimum reduction in the risk of stroke necessary to justify treatment; and two scenarios (one warfarin, one aspirin) determined the maximum acceptable increase in the risk of bleeding.

Determining thresholds

In each scenario we used a probability trade-off with the elicitation method of “ping-ponging” to determine participants’ thresholds (fig 1). This method involved alternating between high and low reductions in risk of stroke in two scenarios and high and low increases in risk of bleeding in two scenarios. All scenarios started with a statement of the baseline risk—“without any antithrombotic treatment there is a baseline risk of major or minor stroke over the next two years of 12 patients out of 100 and a risk of severe bleeding over the next two years of three patients out of 100.” We based the risk of stroke on the average event rate for patients with one or more risk factors in the control arm of pooled analysis from five randomised controlled trials on atrial fibrillation³ and the risk of bleeding on the average rate of bleeding in the control arm of six randomised controlled trials on atrial fibrillation.^{3 15}

Stroke threshold for warfarin

We have used the scenario for determining the minimum reduction in likelihood of stroke necessary to justify the use of warfarin (that is, the stroke threshold for warfarin) to show how we determined a participant’s threshold. Throughout this scenario the rate of episodes of severe bleeding with warfarin was fixed at five in 100 patients over two years (based on the pooled analysis of six randomised controlled trials).^{3 15}

The first flip chart presented the baseline risk and physicians or patients decided whether they would be willing to recommend or take warfarin if it decreased the risk of major or minor stroke over the next two years to 0 out of 100, given the increase in risk of

bleeding (fig 1). If they refused to recommend or take warfarin, the scenario was completed and the threshold was infinity. If they agreed to recommend or take warfarin, they viewed the next flip chart. The baseline risk was repeated, and they then decided whether they would be willing to recommend or take warfarin if it decreased the risk of major or minor stroke over the next two years to 11 out of 100, given the increased risk of bleeding. If they now agreed to recommend or take warfarin, the scenario was completed and their threshold was 1 (that is, the difference between 12 and 11 strokes). If they refused to recommend or take warfarin, the next flip chart asked whether they would be willing to recommend or take warfarin if it decreased the risk of major or minor stroke over the next two years to one out of 100, given the increase in risk of bleeding. The flip charts continued “ping-ponging” the risk of stroke between high and low values until we determined the minimum reduction in the risk of stroke at which the participant would recommend or take warfarin.

Remaining thresholds

To determine the remaining three thresholds, the baseline risk remained fixed. Given that aspirin would increase the risk of severe bleeding from three to 3.3 in 100 (on the basis of data from a large randomised controlled trial of aspirin versus placebo in hypertension¹⁶ because the atrial fibrillation trials had inadequate power to estimate the increased risk of bleeding with aspirin) we then determined the minimum number of strokes that needed to be prevented for a participant to think that taking aspirin was justified (that is, the stroke threshold for aspirin). Given that warfarin would decrease the risk of stroke from 12 to four in 100 (on the basis of a relative risk reduction of 68%³) we then determined the maximum number of episodes of excess severe bleeding that participants were willing to accept (that is, the bleeding threshold for warfarin). Finally, given that aspirin would decrease the risk of stroke from 12 to nine in 100 (on the basis of a relative risk reduction of 21%⁴) we then determined the maximum number of episodes of excess severe bleeding that participants were willing to accept (that is, the bleeding threshold for aspirin).

We did not determine thresholds beyond whole numbers (that is, we did not test any decimal points). For the thresholds determining the maximum increase in episodes of severe bleeding, we tested up to 25 episodes (that is, an increase of 22 episodes).

Sample size

On the basis of work by Man-Son-Hing et al we assumed that on average patients would accept the increased risk of three (SD 1.7) bleeds in 100 patients if warfarin prevented two strokes.¹⁷ We thought it would be a meaningful difference if physicians would accept the increased risk of three bleeds in 100 patients only if warfarin prevented three strokes. A sample size of 46 physicians and 46 patients would provide 80% power to detect such a difference with $\alpha=0.05$ (two sided). Before starting the study we decided to interview 60 physicians and 60 patients.

Data analysis

Our primary analyses compared thresholds of patients and physicians by using the exact test for trend in an

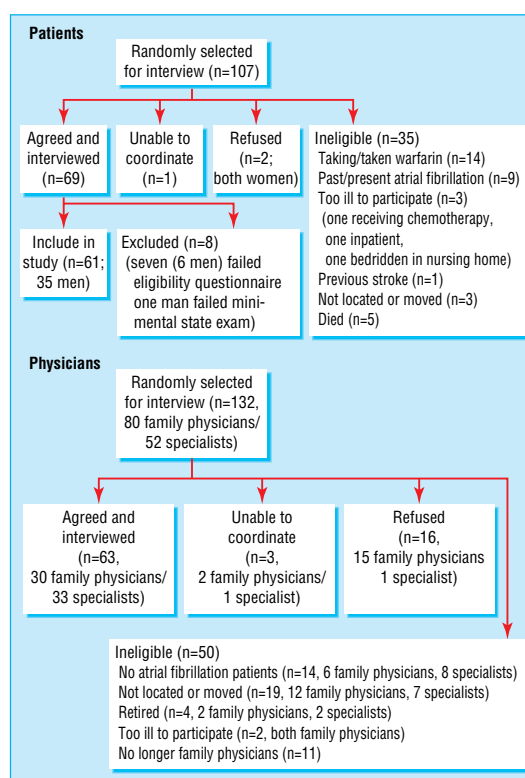


Fig 2 Recruitment and response rate in patients and physicians

$x \times 2$ table, where x denotes the number of rows in the table.^{18 19} We determined means (SD) for both thresholds. We carried out univariate analyses using Spearman's correlation coefficient to determine if there was an association between patients' thresholds and age, sex, location, income, education, mini-mental state score, duration of interview, and randomisation scheme. Similar analyses examined whether any associations existed between physicians' thresholds and specialty, location, years since medical school graduation, number of patients with atrial fibrillation in the preceding year, duration of interview, and randomisation scheme.

Ethics

The research ethics board of Queen Elizabeth II Health Sciences Centre in Halifax, Nova Scotia, approved this study protocol.

Results

Recruitment and characteristics of participants

Figure 2 shows recruitment of participants and reasons for exclusion. Sixty one patients and 63 physicians completed the interview. Table 1 presents patient demographics and socioeconomic status. The mean duration of the interview for patients was 64 minutes (including time for consent and the mini-mental state examination). Table 2 shows demographic details and clinical experience for physicians. The mean duration of the interview with physicians was 25 minutes (consent occurred before the interview, and there was no mini-mental state examination).

Thresholds

Figure 3 shows stroke thresholds for warfarin. Forty five patients (74%) were willing to take warfarin if it

Table 1 Demographic characteristics and socioeconomic status in 61 patients who participated in study of views of physicians and patients on anticoagulation

| Characteristic | No of participants |
|---|--------------------|
| Age (range) (years): | |
| <75 (40-74) | 32 |
| ≥75 (75-93) | 30 |
| No of women | 26 |
| Seen at tertiary referral centre | 30 |
| Education: | |
| Some elementary (age 13 years) | 5 |
| Completed elementary (grade 9, age 14 years) | 10 |
| Some secondary (age 16 years) | 8 |
| Completed secondary (age 17 years) | 9 |
| Some higher | 5 |
| Completed higher | 23 |
| Household income (known for 44 patients) (\$C): | |
| <19 999 | 15 |
| 20-29 999 | 9 |
| 30-49 999 | 13 |
| 50-69 999 | 6 |
| >70 000 | 2 |
| Patients with unknown household income: | |
| No difficulty meeting basic needs | 11 |
| Some difficulty meeting basic needs | 1 |
| Difficulty meeting basic needs | 1 |

prevented just one stroke in 100 patients over a two year period, whereas 24 physicians (38%) were willing to recommend warfarin for the same reduction in stroke ($P=0.009$ for difference between physicians and patients). Figure 4 presents stroke thresholds for aspirin. Most physicians and patients were willing to recommend or take aspirin if it prevented just one stroke ($P=0.29$ for difference between groups).

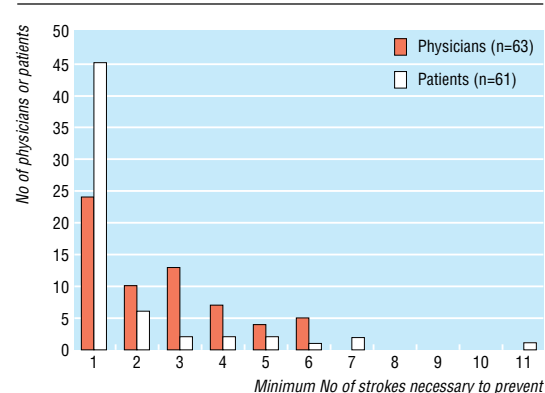
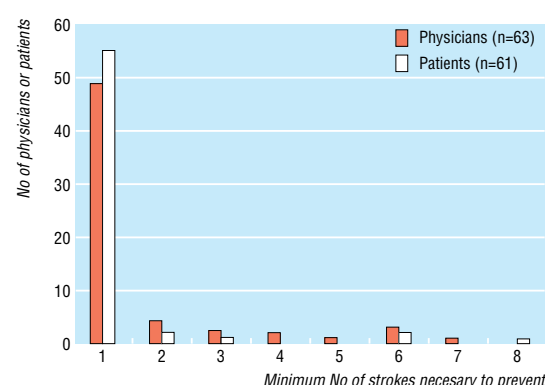
Figure 5 shows bleeding thresholds for warfarin. Thirty five patients (57%) were willing to accept 22 extra episodes of bleeding in 100 patients over a two year period. Physicians' thresholds varied widely ($P<0.001$ for difference between groups). Figure 6 presents bleeding thresholds for aspirin. Again there was wide variability among physicians' thresholds, and 30 of 61 patients (49%) were willing to accept at least 22 extra episodes of bleeding ($P<0.001$ for difference between groups).

The mean threshold for the minimum reduction in risk of stroke in 100 patients over a two year period with warfarin was 2.5 (SD 1.6) for physicians and 1.8 (1.9) for patients. For aspirin the figures were 1.6 (1.5)

Table 2 Demographic characteristics and clinical experience in 63 physicians who participated in study of views of physicians and patients on anticoagulation

| Characteristic | No of physicians |
|--|------------------|
| Family physician | 30 |
| Internist/subspecialist | 33 |
| Location of practice: | |
| Tertiary | 31 |
| Non-tertiary | 32 |
| Mean (range) time since graduation (years) | 20 (2-47) |
| No of patients with AF seen in past year: | |
| 1-5 | 6 |
| 6-10 | 4 |
| 11-20 | 12 |
| 21-30 | 9 |
| >30 | 32 |

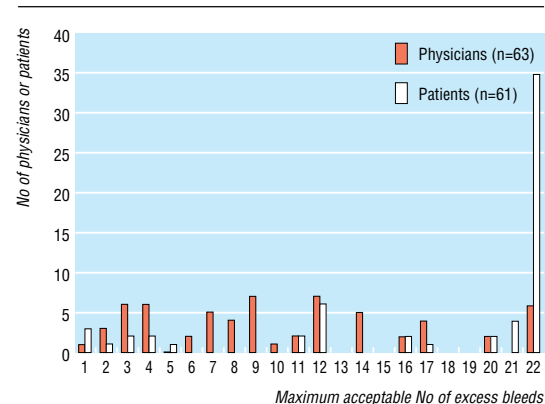
AF=atrial fibrillation.

**Fig 3** Stroke thresholds for warfarin**Fig 4** Stroke thresholds for aspirin

for physicians and 1.3 (1.3) for patients. The mean threshold for the maximum increase in risk of excess bleeding acceptable in 100 patients over a two year period with warfarin was 10.3 (6.1) for physicians and 17.4 (7.1) for patients. For aspirin the figures were 6.7 (6.2) for physicians and 14.7 (8.5) for patients.

Association between participants' factors and thresholds

There was no association between patients' thresholds and any of the factors assessed in the univariate analyses. Physicians who saw more patients with atrial fibrillation were willing to accept a higher number of

**Fig 5** Bleeding thresholds for warfarin

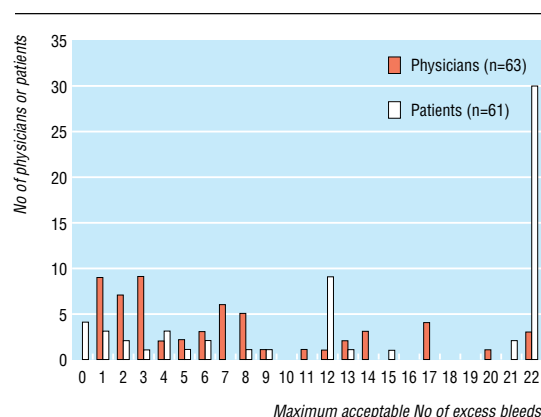


Fig 6 Bleeding thresholds for aspirin

episodes of excess bleeding ($P=0.01$ for warfarin and $P=0.002$ for aspirin).

Discussion

We have shown significant differences between the thresholds of physicians and patients for the risk of excess bleeding deemed acceptable with antithrombotic treatments and the amount of reduction in risk of stroke thought necessary to justify treatment with warfarin.

Strengths and weaknesses

Our study evaluated physicians' thresholds for stroke and excess bleeding, patients' thresholds for excess bleeding, compared thresholds between the two groups, and interviewed patients who had not previously made a decision about antithrombotic treatment but were at high risk of needing to do so in the future. We randomly selected participants from across the province of Nova Scotia, and the response rate was high.

We included those at high risk of atrial fibrillation to provide a group of patients personally at risk of the disease and its ramifications, thus allowing decision making to be relevant and important. Patients with atrial fibrillation who have made a decision about antithrombotic treatment have already received information on the risks and benefits (which may or may not have been accurate). Cognitive dissonance (a state of psychological discomfort due to inconsistent cognitions) could readily lead patients to modify their interpretation of information provided during the study to ensure it was consistent with their previous decision.^{20 21} By excluding patients with atrial fibrillation who had previously made a decision about antithrombotic treatment we avoided this problem.

Potential limitations

Our study has several limitations. Ideally we would have determined thresholds for patients who were newly diagnosed with atrial fibrillation before any input (such as an interaction with their family physician) that may have influenced their decision about antithrombotic treatment. Logistic limitations inhibited our ability to do this. The selection of patients who were at high risk for atrial fibrillation but without a history of use of warfarin, stroke, or major bleeding

provided the best alternative. Given that one individual interviewed physicians and another interviewed patients, interviewer bias may have influenced the results. However, to standardise their approach, the interviewers piloted the entire interview on seven physicians and seven patients together. We also ensured that the wording was neutral in presentation and that both interviewers consistently used the prewritten text. Although we did not establish the stability of the thresholds through a second interview, several investigators have shown that thresholds do remain stable over time.^{17 22–24}

Comparisons with other studies

Several studies have evaluated patients' preferences for antithrombotic treatment in atrial fibrillation. Three studies used probability trade-offs to determine patients' thresholds for reduction in risk of stroke or to assist in management decisions.^{17 25 26} One study interviewed patients who had previously decided to take warfarin, and the thresholds for reduction in risk of stroke were low, as they were in our study.¹⁷ In a second study, with a mix of patients who were and were not taking warfarin, the thresholds showed more variation, with patients not taking warfarin requiring a higher reduction in risk of stroke than those taking warfarin.²⁵ In this study patients who decided not to take warfarin after the interview did not see themselves as at risk, despite the probability trade-off clearly showing such risk.²⁵ This finding suggests that cognitive dissonance played a part in patients' responses. The third study evaluated patients from the SPAF-III (stroke prevention in atrial fibrillation) aspirin cohort.²⁶ Nearly all patients selected aspirin rather than warfarin (there was no option of no treatment), but patients who had previously taken warfarin were more likely to select warfarin than those who had only taken aspirin.²⁶ Once again, cognitive dissonance probably explains the differences between these results and ours.

Two studies used another method (decision analysis) to incorporate patients' preferences into decision making and, as in our study, found that patients placed a high value on avoiding stroke and a much lower value on avoiding a bleed.^{27 28} Despite this, both decision analyses suggested that patients may be less likely to want warfarin treatment than our results suggest. However, in one decision analysis their model was sensitive to patients' feelings about monitoring anticoagulation, and for patients with no disutility associated with the inconvenience of treatment, warfarin was preferred by virtually all patients.²⁸ One study directly compared decision analytic modelling with probability trade-off techniques; it showed that recommendations regarding treatment vary significantly depending on which method is used.²⁹ After patients were presented with their individual treatment thresholds as determined by both methods, over twice as many patients stated that they would base their preferences on the results of the probability trade-off as opposed to the decision analysis.²⁹ Further research should compare these methods directly.

Implications

The average decrease in the absolute risk of stroke that participants required for them to recommend or take warfarin (physicians 2.5%, patients 1.8%) and aspirin (physicians 1.6%, patients 1.3%) could be achieved by

What is already known on this topic

Several observational studies have shown an apparent underuse of antithrombotic drugs in patients with atrial fibrillation, despite evidence of efficacy

What this study adds

There is considerable variability between physicians and patients in their weighing up of the potential outcomes associated with atrial fibrillation and its treatment

For anticoagulation treatment to be acceptable patients required less reduction in risk of stroke and were more tolerant of an increase in risk of bleeding than physicians

Physicians varied considerably in how much risk of bleeding they thought was acceptable for a given reduction in risk of stroke associated with antithrombotic drugs

treating patients older than 65 years or those with one or more associated risk factors for cardioembolic events.

The most striking variability between physicians and patients was in the thresholds for risk of bleeding with warfarin and aspirin. Patients were willing to accept a much higher risk of bleeding for an associated reduction in risk of stroke. Physicians as a group showed little consistency as to how much risk of excess bleeding was acceptable. This variability may be accounting for some of the underuse of antithrombotic drugs.⁶⁻¹⁰ Physicians may make strong recommendations against warfarin or not offer warfarin as a treatment if they think the risks outweigh the benefits.

In summary we have shown considerable variability between physicians and patients in their weighing up of the potential outcomes associated with atrial fibrillation and its treatment. Patients' preferences should be incorporated into decisions about antithrombotic treatment in atrial fibrillation. If physicians make decisions about management without such input then they risk finding themselves out of step with the people whose care they are striving to optimise.

Contributors: PJD was involved in the conception, design, data collection, and interpretation of data. He also drafted the article and will act as guarantor for this study. DRA and JLC were involved in the conception, design, interpretation of data, revisions of the article, and supervision of the project. MJG, WP, and SN were involved in the conception, design, interpretation of data, and revisions of the article. CJF was involved in analyses, interpretation of the data, and revisions of the article. BFB was involved in data collection, interpretation of the data, and revisions of the article.

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Commentary: Varied preferences reflect the reality of clinical practice

Tom Fahey

This study by Devereaux et al is an important addition to the expanding literature on shared decision making between patients and health professionals. It shows that patients may be more averse to the potential consequences of stroke and less bothered by the side effects of antithrombotic treatment than doctors are. It also shows that individual responses in both groups vary substantially. Responses for the minimum number of strokes that need to be prevented before warfarin is acceptable ranged from one to six for doctors and one to 11 for patients. For aspirin the figures were one to seven for doctors and one to eight for patients. Individual responses to the maximum number of excess bleeds that would be acceptable was even more diverse, ranging from one to 22 in both doctors and patients for both forms of antithrombotic treatment. These findings are consistent with other observational studies that have compared the preferences of patients and health professionals when they are faced with choices about treatment. Differences in such preferences are difficult to predict, vary in direction and magnitude, and are often specific for a given condition.¹

Devereaux et al highlight potential biases that might account for the reported difference in responses in their study. These biases include non-blinded interviewers questioning each of the two groups separately (interviewer bias) and the fact that patients' interviews lasted considerably longer (even with allowance for consent and the mini-mental test undertaken in the patient group alone). Furthermore, selection of patients who had no experience of either a stroke or side effects of treatment might bias their results. Patients who have experienced an episode of bleeding due to warfarin treatment report significantly lower quality of life scores.² Many would argue that it is not surprising that differences in preferences for antithrombotic treatment were found. Patients seem to be older and have lower educational attainment than the

doctors taking part in this study. Differences in characteristics between patients and doctors may have produced differences in preferences for antithrombotic treatment. This is precisely the reason why health professionals should explicitly seek patients' views when they are making decisions about treatment. Unfortunately, asking patients about their preferences for treatment when decisions are being made on future management is often neglected by doctors.³

Important developments are likely to alter the dynamics of decision making between patients and doctors in the future. Information is now a freely available commodity. Initiatives such as the Cochrane collaboration actively promote consumer involvement and patient orientated information about medical effectiveness. Decision aids and other tools are being developed that will give patients access to information and allow them to express their preferences for treatment options.⁴ Some clinical guidelines explicitly express and quantify the impact of patients' preferences on recommendations for treatment.⁵ The findings from this study show that health professionals should be sensitive to patients' preferences and encourage the use of decision aids and information sources that can facilitate shared decision making.

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