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) vs 2.5 (1.6), P = 0.009), whereas for aspirin there was no difference between patients and physicians (1.3 (1.3) vs 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) vs 10.3 (6.1); aspirin 14.7 (8.5) vs 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 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 arrhythmia and is a major risk factor for stroke. Clinical trials have shown that warfarin and to a lesser extent aspirin 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, an apparent underuse of antithrombotic drugs in these patients.

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

Participants—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. Exclusion criteria included: history of atrial fibrillation; current or previous use of warfarin; previous stroke; previous severe bleeding. Patients with a history of aspirin use were not excluded as the use of aspirin is so ubiquitous in this patient population. We randomly selected family physicians and general internists or subspecialists from the physician registry of the Department of Health, Nova Scotia.

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 (for an example of a chart see the full version of this paper on the BMJ’s website).

The two people who interviewed the patients (BBF) and physicians (PJD) followed prewritten text during the interview.

Baseline information—Participants read flip charts describing major and minor stroke, major and minor bleeding, and inconveniences and costs of treatments. We told participants that the likelihood of a minor or major stroke was equal. We described the most common type of major bleed: a non-fatal gastrointestinal bleed.

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. In each scenario we used a probability trade-off with the elicitation method of “ping-ponging” to determine participants’ thresholds. 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.\textsuperscript{6} 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 fibrillation\textsuperscript{7} and the risk of bleeding on the average rate of bleeding in the control arm of six randomised controlled trials on atrial fibrillation.\textsuperscript{3, 11}

Sample size—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.\textsuperscript{15} 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).

Data analysis—Our primary analyses compared thresholds of patients and physicians by using the exact test for trend in an $x\times 2$ table.\textsuperscript{16, 17} 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.

Results

Recruitment and characteristics of participants

Figure 1 shows recruitment of participants and physicians as well as reasons for exclusion. 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

Forty five patients (74%) were willing to take warfarin if it 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 ($P = 0.069$ for difference between physicians and patients) (fig 2). Most physicians and patients were willing to recommend or take aspirin if it prevented just one stroke ($P = 0.29$).

For treatment with warfarin, 35 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 treatment with 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 ($P < 0.001$).

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) for physicians and 1.5 (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.
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.

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, as determined by both methods, 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 prescriptive 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.\textsuperscript{15-18-20}

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 decision making.\textsuperscript{15 21 22} In one study the thresholds for reduction in risk of stroke were comparable with those in our study.\textsuperscript{23} 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.\textsuperscript{21} The third study evaluated patients from the SPAF-III (stroke prevention in atrial fibrillation) aspirin cohort.\textsuperscript{22} 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.\textsuperscript{22} 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.\textsuperscript{21 23} 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.\textsuperscript{22} 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.\textsuperscript{23} 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.\textsuperscript{23} Further research should compare these methods directly.

Implications

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.\textsuperscript{22-23} 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 fibrilla-

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

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No of physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family physician</td>
<td>30</td>
</tr>
<tr>
<td>Internist/subspecialist</td>
<td>33</td>
</tr>
<tr>
<td>Location of practice</td>
<td></td>
</tr>
<tr>
<td>Tertiary</td>
<td>31</td>
</tr>
<tr>
<td>Non-tertiary</td>
<td>32</td>
</tr>
<tr>
<td>Mean (range) time since graduation (years)</td>
<td>20 (2-47)</td>
</tr>
<tr>
<td>No of patients with AF seen in past year.</td>
<td></td>
</tr>
<tr>
<td>1-5</td>
<td>6</td>
</tr>
<tr>
<td>6-10</td>
<td>4</td>
</tr>
<tr>
<td>11-20</td>
<td>12</td>
</tr>
<tr>
<td>21-30</td>
<td>9</td>
</tr>
<tr>
<td>&gt;30</td>
<td>32</td>
</tr>
</tbody>
</table>

AF=atrial fibrillation.
4 Atrial Fibrillation Investigators. The efficacy of aspirin in patients with warfarin is acceptable ranged from one to six for variability. Responses for the minimum number of strokes that need to be prevented before warfarin is acceptable ranged from one to six for physicians and patients in their weighing up of the potential outcomes associated with atrial fibrillation and its treatment. 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.

**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.

**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. Competing interests: None declared.


Laparoscopic performance after one night on call in a surgical department: prospective study

Teodor P Grantcharov, Linda Bardram, Peter Funch-Jensen, Jacob Rosenberg

Surgeons often operate during the night, and often after disturbed sleep or total lack of sleep. Impairment of surgical dexterity due to fatigue could lead to mistakes that are life threatening for the patient. Our study investigated the hypothesis that one night on call in a surgical department would adversely affect the surgeon’s performance on simulated laparoscopic tasks.

Participants, methods, and results

The study was carried out in a gastroenterological surgical unit at a teaching hospital. A night shift started at 3.30 pm and finished at 9 am the following day. A total sleep time of less than three hours was necessary for inclusion in the study.

All 14 surgeons in training at our department—11 men and three women—participated in the study. The median age was 34 (range 24-43) and the median time since graduation was six years (1-11 years). All trainees had similar, limited experience in laparoscopic surgery; the median number of cholecystectomies they had performed was 0 (0-5). All participants received identical pretraining on the minimally invasive surgical trainer-virtual reality (MIST-VR, Mentine Medical Simulation, Gothenburg, Sweden) by performing nine repetitions of six tasks.¹ ² The laparoscopic surgical skills of the 14 trainees were assessed on the 10th repetition of the task, which was performed during normal daytime working hours and again at 9.30 am after a night on call with impaired sleep. The period between the first and 10th repetition on the MIST was predetermined to be no longer than one month.

We analysed the data using non-parametric analysis (Wilcoxon test). We examined the difference between scores for error of motion, time of motion, and economy of motion measured during the 10th repetition of the task in the daytime and after a night on call.

The median total sleep time during the night on call was 1.5 hours (0-5 hours). After a night on call the time taken to complete the virtual laparoscopic tasks (P ≤ 0.006) increased significantly for tasks 1, 3, 4, 5, and 6 (5.4 v 7.6 seconds, 5.6 v 7.8 seconds, 6.7 v 8.1 seconds, 15.0 v 18.1 seconds, and 18.2 v 23.8 seconds, respectively), and after a night shift surgeons performed significantly more errors in tasks 1 and 6 (0.6 v 1.0, P = 0.01; and 1.4 v 3.5, P = 0.005, respectively). The number of unnecessary movements for tasks 5 and 6 increased significantly after a night on call.