ORIGINAL RESEARCH

Differences in Perceived and Predicted Bleeding Risk in Older Adults With Atrial Fibrillation: The SAGE-AF Study

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BACKGROUND: Little research has evaluated patient bleeding risk perceptions in comparison with calculated bleeding risk among oral anticoagulant users with atrial fibrillation. Our objective was to investigate underestimation of bleeding risk and to describe the characteristics and patient-reported outcomes associated with underestimation of bleeding risk.

METHODS AND RESULTS: In the SAGE-AF (Systematic Assessment of Geriatric Elements in Atrial Fibrillation) study, a prospective cohort study of patients ≥65 years with atrial fibrillation, a CHA_2DS_2-VASc risk score ≥2 and who were on oral anticoagulant therapy, we compared patients' self-reported bleeding risk with their predicted bleeding risk from their HAS-BLED score. Among the 754 participants (mean age 74.8 years, 48.3% women), 68.0% underestimated their bleeding risk. Participants who were Asian or Pacific Islander, Black, Native American or Alaskan Native, Mixed Race or Hispanic (non-White) (adjusted OR [AOR], 0.45; 95% CI, 0.24–0.82) and women (AOR, 0.62; 95% CI, 0.40–0.95) had significantly lower odds of underestimating their bleeding risk than respective comparison groups. Participants with a history of bleeding (AOR, 3.07; 95% CI, 1.73–5.44) and prior hypertension (AOR, 4.33; 95% CI, 2.43–7.72), stroke (AOR, 5.18; 95% CI, 1.87–14.40), or renal disease (AOR, 5.05; 95% CI, 2.98–8.57) had significantly higher odds of underestimating their bleeding risk.

CONCLUSIONS: We found that more than two-thirds of patients with atrial fibrillation on oral anticoagulant therapy underestimated their bleeding risk and that participants with a history of bleeding and several comorbid conditions were more likely to underestimate their bleeding risk whereas non-Whites and women were less likely to underestimate their bleeding risk. Clinicians should ensure that patients prescribed oral anticoagulant therapy have a thorough understanding of bleeding risk.

Key Words: anticoagulant ■ atrial fibrillation ■ bleeding risk perception ■ predicted bleeding risk

Atrial fibrillation is the most common cardiac arrhythmia, prevalent in an estimated 5 million adults in the United States.[1] Guidelines for the management of patients with atrial fibrillation recommend lifelong oral anticoagulant (OAC) therapy as cornerstone therapy for stroke prevention.[2] Optimal medication adherence is crucial to successful OAC therapy and can reduce the risk of stroke and associated mortality by upwards of three-quarters and one-quarter in patients with atrial fibrillation, respectively.[3,4] Bleeding is a common concern among providers and patients before initiation of and during OAC therapy.[5,6] However, little research has evaluated patients' perceptions of their risk for bleeding in comparison with calculated bleeding risk using risk assessment algorithms.

Evaluating the extent of discordance between patient bleeding risk perceptions and calculated bleeding risk has important clinical implications. Bleeding

CLINICAL PERSPECTIVE

What Is New?

- In a contemporary cohort of older adults with atrial fibrillation on oral anticoagulants, 67% of adults underestimated their bleeding risk.
- Races and ethnicities other than non-Hispanic White (Asian or Pacific Islander, Black, Native American or Alaskan Native, Mixed Race or Hispanic) and women had significantly lower odds of underestimating their bleeding risk, whereas participants with a history of bleeding and with previously diagnosed hypertension, stroke, and renal disease had significantly higher odds of underestimating their bleeding risk.
- Atrial fibrillation knowledge was not associated with underestimating bleeding risk.

What Are the Clinical Implications?

- Patients with misperceptions of their bleeding risk may be unable to engage in informed treatment decision making and may be more at risk for nonadherence to monitoring activities and lifestyle modifications necessary for successful anticoagulation.
- As knowledge was not associated with underestimating bleeding risk perceptions, clinicians should consider educational strategies that focus on strengthening provider–patient relationships that may help align patient bleeding risk perceptions with predicted bleeding risk.

Nonstandard Abbreviations and Acronyms

OAC   oral anticoagulant
SAGE-AF Systematic Assessment of Geriatric Elements in Atrial Fibrillation

risk discordance may affect a patient's decision to initiate OAC therapy, adherence to monitoring procedures, and adherence to dosing recommendations and protocols. Further, understanding bleeding risk discordance may identify patients at high risk for poor medication adherence who might benefit from more education and counseling regarding their personal bleeding risk. The objectives of this study were to determine the proportion of older users of OAC therapy who underestimate their bleeding risk and to describe the characteristics and patient-reported outcomes associated with underestimation of bleeding risk.

METHODS

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Data are drawn from the SAGE-AF (Systematic Assessment of Geriatric Elements in Atrial Fibrillation) study. The SAGE-AF study has been described previously.[7,8] In brief, 1244 participants were recruited from 5 ambulatory care sites in Massachusetts and Georgia between 2015 and 2018. Patients were eligible for study enrollment if they had a history of atrial fibrillation; were 65 years or older; had a CHA_2DS_2-VASc (congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category) risk score ≥2; and were taking or eligible for OAC therapy with no contraindication to OAC therapy. This report includes participants who participated in the year 1 follow-up (n=1097) and were taking an OAC (n=754). Data were collected through structured in-person interviews and medical record reviews at 1-year follow-up by trained study staff. Participants were ineligible for enrollment if they did not demonstrate the capacity to provide informed consent. This was assessed by 8 questions regarding the risks and benefits of the study, voluntary nature of participation, and the confidential nature of all study data. All participants provided written informed consent. The study was approved by the institutional review boards of The University of Massachusetts Medical School, Mercer University and Boston University.

Participant Characteristics

Participant characteristics including demographic, clinical, and geriatric element measures were collected at baseline through medical record abstraction and structured interviews. Frailty was assessed using the Cardiovascular Health Survey frailty scale.[9] Cognitive impairment was measured using the Montreal Cognitive Assessment Battery designed to detect mild cognitive impairment with a cutoff point of 23 to designate impairment.[10,11] Social support was measured using the Medical Outcomes Social Support Survey Instrument with a score of 12 or more indicating social isolation.[12] Visual and hearing impairment were based on patient self-report using standardized questionnaires. Depression was measured using the Patient Health Questionnaire-9 and anxiety was assessed using the Generalized Anxiety Disorder-7 scale.[13,14] A cutoff score of 5 was used for both measures representing mild depressive and anxiety symptoms.[13,14] To measure participants' personal bleeding risk knowledge, participants were asked to rate their bleeding risk knowledge as very knowledgeable, somewhat knowledgeable, a little bit

of knowledge, or no knowledge. Patients' knowledge of atrial fibrillation was assessed using the Jessa Atrial Fibrillation Questionnaire.[15]

Predicted Bleeding Risk

The HAS-BLED (hypertension, abnormal renal and liver function, stroke, bleeding, labile international normalized ratio, elderly, and drugs or alcohol) score was used to predict 1-year risk of major bleeding for each study participant.[16] Baseline patient data were used to calculate the HAS-BLED score for each participant. HAS-BLED scores range from 0 to 9 with 9 representing the greatest 1-year risk of major bleeding.[16] Guidelines recommend using a HAS-BLED cutoff point of ≥3, representing higher risk patients (≥5.8% annual risk of a major bleeding event) to identify patients with atrial fibrillation on OAC who may need regular or closer follow-up.[17] Therefore, a cutoff point of 3 was used in the present study to separate participants into predicted bleeding risk categories.

Patient-Perceived Bleeding Risk

Patient-perceived bleeding risk was assessed at 1-year follow-up using the following questions, "If you are taking an anticoagulant, what do you think your annual risk of having a major bleeding episode (eg, around your heart, in your brain, in your stomach or colon) on this medicine is?" Responses were categorized according to HAS-BLED scores where 0 to 2 represented "no chance of a bleeding event in the next year"; low chance of a bleeding event in the next year (1%);" and "moderate chance of a bleeding event in the next year (2–3%)." HAS-BLED scores ≥3 represented patient responses "high chance of a bleeding event in the next year (4%–8%)" and "very high chance of a bleeding event in the next year (>9%)." These definitions are dichotomized categories of similar definitions used in previous studies. Zweiker et al defined risk where a HAS-BLED 0–1 represented the low-risk group, bleeding rate 0% to 4%/year; HAS-BLED 2 represented the intermediate risk group, bleeding rate 4% to 6%/year; HAS-BLED 3–4 represented the high-risk group, bleeding rate 6% to 10%/year; and a HAS-BLED ≥5 represented the very high-risk group, bleeding rate >10%/year.[18] Similarly, though Hijazi et al did not use qualitative descriptors of risk, they defined risk where a HAS-BLED 1 corresponded to 1% to 3% risk, HAS-BLED 2 or 3 to 4% to 6% risk, HAS-BLED 4 or 5 7% to 10% risk, and HAS-BLED 6 or 9% to ≥10% risk.[19] Through the dichotomized categories described earlier, the present study aligns with guideline recommendations where a HAS-BLED score ≥3 represents a patient at higher risk for a major bleeding event.[17] Bleeding risk concordance was defined as when participants perceived bleeding risk was aligned with their predicted bleeding risk using the HAS-BLED risk assessment algorithm.

Statistical Analysis

The data were analyzed descriptively using proportions for categorical variables and means for continuous variables. Differences in patient characteristics and patient-reported outcomes between participants who correctly estimated their bleeding risk and those who underestimated their bleeding risk were evaluated using t tests for continuous variables and χ^2 tests for categorical variables. Multivariable logistic regression was used to evaluate patient characteristics that were independently associated with underestimating bleeding risk, adjusting for characteristics that differed significantly in the t tests and χ^2 tests (sex, marital status, heart failure, peripheral vascular disease, hypertension, stroke, anemia, renal disease, history of bleeding, and CHA_2DS_2-VASc score) and additional characteristics that the authors deemed relevant from their clinical experience (age, race/ethnicity, education, time since atrial fibrillation diagnosis, informed by provider of risk, frailty, cognitive impairment, self-rated personal bleeding risk knowledge and Jessa atrial fibrillation knowledge questionnaire). Unadjusted and adjusted odds ratios (ORs) and 95% CIs are used to report the results of the multivariate logistic regression analysis. A priori statistical significance was set at $P<0.05$ for all statistical analyses. All analyses were performed using SAS version 9.4 (SAS Institute, Inc, Cary, NC).

RESULTS

There were a total of 754 SAGE-AF participants on OAC therapy who completed the 1-year interview. The mean age of this study sample was 74.8±6.6 years, 48% (n=364) were women and 86% (n=651) of participants were non-Hispanic White. The mean HAS-BLED score of the study sample was 3.2±1.1 and 42% of participants (n=317) were on direct OACs.

The majority of study participants (69%; n=523) reported bleeding risk perceptions that differed from their predicted bleeding risk and among these participants, about 2% (n=10) overestimated their bleeding risk (ie, patient-reported perceived bleeding risk was higher than the HAS-BLED predicted bleeding risk) and nearly all (98%; n=513) underestimated their bleeding risk (ie, patient-reported perceived bleeding risk was lower than the HAS-BLED predicted bleeding risk). A distribution of perceived and predicted bleeding risk is presented in Figure S1. A significantly higher proportion of those who underestimated their bleeding risk were married or living as married (61%) and had a history of bleeding (23%) compared with those

who correctly estimated their bleeding risk (51% and 8%, respectively, Table 1). A significantly higher proportion of those who correctly estimated their bleeding risk were women, whereas participants with medical comorbidities of heart failure, peripheral vascular disease, hypertension, stroke, anemia, and renal disease, and those with higher CHA_2DS_2-VASc scores were significantly more likely to underestimate their bleeding risk (Table 1).

Multivariable logistic regression results (unadjusted and adjusted ORs) are presented in Table 2. In the unadjusted model, women were significantly less likely to underestimate their bleeding risk (unadjusted OR, 0.62; 95% CI, 0.46–0.85). Conversely, participants who were married or living as married (unadjusted OR, 1.49; 95% CI, 1.09–2.03), had a history of bleeding (unadjusted OR, 3.30; 95% CI, 1.97–5.50) and higher CHA_2DS_2-VASc scores (unadjusted OR, 1.33; 95% CI, 1.19–1.48) had significantly higher odds of underestimating their bleeding risk. Additionally, in the unadjusted model, participants with the comorbidities of heart failure (unadjusted OR, 1.41; 95% CI, 1.01–1.97), peripheral vascular disease (unadjusted OR, 1.90; 95% CI, 1.15–3.16), hypertension (unadjusted OR, 5.26; 95% CI, 3.15–8.76); stroke (unadjusted OR, 7.02; 95% CI, 2.79–17.66), anemia (unadjusted OR, 1.52; 95% CI, 1.07–2.15), and renal disease (unadjusted OR, 5.31; 95% CI, 3.30–8.54) had significantly higher odds of underestimating their bleeding risk. After multivariable adjustment, participants who were Asian or Pacific Islander, Black, Native American or Alaskan Native, Mixed Race or Hispanic (non-White) were 55% less likely to underestimate their bleeding risk compared with Whites (adjusted OR, 0.45; 95% CI, 0.24–0.82) and women were 38% less likely to underestimate their bleeding risk compared with men (adjusted OR, 0.62; 95% CI, 0.40–0.95). In addition, study participants with a history of bleeding (adjusted OR, 3.07; 95% CI, 1.73–5.44), hypertension (adjusted OR, 4.33; 95% CI, 2.43–7.72), stroke (adjusted OR, 5.18; 95% CI, 1.87–14.40), and renal disease (adjusted OR, 5.05; 95% CI, 2.98–8.57) had significantly higher odds of underestimating their bleeding risk.

DISCUSSION

This study of 754 older adults with atrial fibrillation on OAC medication found that nearly 70% of patients underestimated their bleeding risk. Because bleeding is a frequent complication of OAC use, it is important that patients are well informed regarding their bleeding risk to enable and promote informed decision making, medication adherence, necessary lifestyle changes, and appropriate drug monitoring.[20] We found that races and ethnicities other than non-Hispanic White and women had significantly lower odds of underestimating

their bleeding risk, whereas participants with a history of bleeding and with previously diagnosed hypertension, stroke, and renal disease had significantly higher odds of underestimating their bleeding risk.

To our knowledge, only 2 other studies have compared patient perceived bleeding risk and predicted bleeding risk. In a study of 91 newly diagnosed patients with atrial fibrillation (mean age=73 years, 45% women) by Zweiker et al, 59% of participants incorrectly estimated their bleeding risk and of those who incorrectly estimated their bleeding risk, 57% overestimated their risk.[18] In a study of 227 patients with atrial fibrillation (mean age=72 years, 45% women) by Hijazi et al, 53% of patients overestimated their bleeding risk, reporting higher than a 10% risk of bleeding.[19]

Our findings offer a unique contribution to the limited literature regarding patient bleeding risk perceptions. In contrast with previously published work, our study included a large and representative sample of contemporary patients with various types of atrial fibrillation, treated with both direct OACs and vitamin K antagonists and seen by multiple types of healthcare providers in geographically diverse practice locations. We found that among patients who incorrectly estimated their bleeding risk, nearly all participants underestimated their bleeding risk. Differences between our findings and previous studies could be related to key differences in study samples and questionnaires used to collect data. Hijazi et al reported that 41% of their participants had a history of bleeding compared with 18% of participants in the present study. It is possible that a history of bleeding might lead to overestimation of bleeding risk as there is evidence that previous experience is a strong predictor of higher risk perception.[21] Zweiker et al reported that among their smaller sample (n=91) of participants who had not initiated OAC therapy at the time of study initiation, only 1% of patients reported a history of bleeding. Patients in previous studies also included participants with lower calculated bleeding risk than those included in the present study. In the studies by Hijazi et al and Zweiker et al, 46% and 19% of participants, respectively, had HAS-BLED scores ≥3 compared with 73% in the present study. This difference in calculated bleeding risk may have also led to more overestimation in previous studies. In addition to these differences, past study samples either consisted of newly diagnosed patients who had not started OAC therapy or a mixture of patients with atrial fibrillation, irrespective of their OAC status.

Our study sample of older adults with confirmed atrial fibrillation may be more representative of the general landscape of patient bleeding risk perceptions among OAC users in the United States. Additionally, our study sample includes patients receiving care from cardiologists, electrophysiologists, and internists, whereas previous studies surveyed participants

Table 1. Sample Characteristics by Correctly Estimated and Underestimated Bleeding Risk: The SAGE-AF Study

Characteristic	Correctly Estimated Bleeding Risk (n=231)	Underestimated Bleeding Risk (n=513)	P Value
Age, y, mean (SD)	74.3 (6.7)	75.0 (6.5)	0.14
Race/ethnicity other than non-Hispanic White[§]	34 (14.7)	65 (12.7)	0.45
Female sex	130 (56.3)	228 (44.4)	0.003*
Married or living as married	117 (50.9)	309 (60.6)	0.01*
Education[†]			
College graduate or more	110 (47.6)	213 (41.8)	0.14
Living situation[‡]			
With spouse or others	163 (70.6)	376 (73.7)	0.37
Medical comorbidities			
Heart failure	70 (30.3)	195 (38.0)	0.04*
Coronary artery disease	40 (17.3)	106 (20.7)	0.29
Peripheral vascular disease	21 (9.1)	82 (16.0)	0.01*
Hypertension	182 (78.8)	488 (95.1)	<0.001*
Diabetes mellitus	57 (24.7)	138 (26.9)	0.52
Dyslipidemia	175 (75.8)	420 (81.9)	0.05
Stroke	5 (2.2)	69 (13.5)	<0.001*
Anemia	58 (25.1)	173 (33.7)	0.02*
Asthma/chronic obstructive pulmonary disease	58 (25.1)	132 (25.7)	0.86
Renal disease	22 (9.5)	184 (35.9)	<0.001*
Implantable cardiac device	73 (31.6)	179 (34.9)	0.38
Clinical characteristics			
AF Type–paroxysmal	139 (65.3)	295 (64.7)	0.89
Time since AF diagnosis, y, mean (SD)	5.2 (4.3)	5.5 (4.4)	0.27
History of bleeding	19 (8.2)	117 (22.8)	<0.001*
CHA_2DS_2-VASc score, mean (SD)	3.9 (1.4)	4.6 (1.6)	<0.001*
Treatment characteristics			
Type of OAC–Direct OAC	91 (39.4)	221 (43.1)	0.35
Aspirin use	68 (29.4)	157 (30.6)	0.75
Antiplatelet use	15 (6.5)	24 (4.7)	0.30
Provider type			
Cardiologist	93 (40.3)	224 (43.7)	0.61
Electrophysiologist	134 (58.0)	278 (54.2)	
Internist	4 (1.7)	11 (2.1)	
Informed by provider of risk	197 (86.4)	434 (85.3)	0.68
Geriatric elements			
Frailty			
Frail	19 (8.2)	62 (12.1)	0.29
Pre-frail	126 (54.6)	270 (52.6)	
Not frail	86 (37.2)	181 (35.3)	
Cognitive Impairment	81 (35.1)	189 (36.8)	0.64
Social support	34 (14.7)	55 (10.7)	0.12
Visual impairment	75 (32.5)	165 (32.2)	0.93
Hearing impairment	68 (29.4)	181 (35.3)	0.12
Depression	60 (26.0)	128 (25.0)	0.77
Anxiety	53 (22.9)	111 (21.6)	0.69

Continued

Table 1 Continued

Characteristic	Correctly Estimated Bleeding Risk (n=231)	Underestimated Bleeding Risk (n=513)	P Value
Self-rated knowledge of bleeding risk			
No to little knowledge	37 (16.1)	92 (17.9)	0.54
Some to very knowledge	193 (83.9)	421 (82.1)	
Jessa AF knowledge questionnaire, mean (SD)	67.4 (15.3)	66.4 (15.6)	0.44

Continuous variables are presented as mean±SD and categorical variables are presented as n (%). AF indicates atrial fibrillation; CHA_2DS_2-VASc, congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category; OAC, oral anticoagulant; and SAGE-AF, Systematic Assessment of Geriatric Elements in Atrial Fibrillation.

*Statistical significance $P<0.05$.

†College graduate or more=college graduate; graduate degree.

‡With spouse or others=with spouse; with family other than spouse; with people other than family; nursing home.

§Asian or Pacific Islander, Black, Native American or Alaskan Native, Mixed Race or Hispanic.

receiving care from cardiologists alone. Lastly, previous studies collected bleeding risk perception data using questions that either gave only numerical risk ranges (eg, 1%–3%, 4%–6%) or descriptive risk estimates (eg, low, intermediate). Adhering to health literacy best practices, our survey questions used both interpretive framing (eg, high chance, low chance) and numbers to communicate bleeding risk.[22]

Table 2. Logistic Regression Analysis of Underestimating Bleeding Risk: The SAGE-AF Study

Characteristic	Unadjusted OR (95% CI)	Adjusted Model OR (95% CI)
Age, y	1.02 (0.99–1.04)	1.00 (0.97–1.03)
Race/ethnicity other than non-Hispanic White‡	0.84 (0.54–1.32)	0.45 (0.24–0.82)*
Female sex	0.62 (0.46–0.85)*	0.62 (0.40–0.95)*
Married or living as married	1.49 (1.09–2.03)*	1.41 (0.94–2.11)
Education†		
College graduate or more	0.79 (0.58–1.08)	0.74 (0.51–1.10)
Medical comorbidities		
Heart failure	1.41 (1.01–1.97)*	0.94 (0.59–1.50)
Peripheral vascular disease	1.90 (1.15–3.16)*	0.88 (0.47–1.63)
Hypertension	5.26 (3.15–8.76)*	4.33 (2.43–7.72)*
Stroke	7.02 (2.79–17.66)*	5.18 (1.87–14.40)*
Anemia	1.52 (1.07– 2.15)*	1.06 (0.70–1.61)
Renal disease	5.31 (3.30–8.54)*	5.05 (2.98–8.57)*
Clinical and treatment characteristics		
Time since AF diagnosis	1.02 (0.98–1.06)	0.99 (0.95–1.04)
History of bleeding	3.30 (1.97–5.50)*	3.07 (1.73–5.44)*
CHA_2DS_2-VASc score	1.33 (1.19–1.48)*	1.17 (0.96–1.41)
Informed by provider of risk	0.91 (0.58–1.43)	1.01 (0.58–1.74)
Geriatric elements		
Frailty		
Frail	1.55 (0.87–2.75)	0.87 (0.42–1.79)
Pre-frail	1.02 (0.73–1.42)	0.86 (0.58–1.28)
Not frail	Ref	Ref
Cognitive Impairment	1.08 (0.78–1.49)	0.80 (0.53–1.22)
Self-rated personal bleeding risk knowledge		
No to little knowledge	Ref	Ref
Some to very knowledge	0.88 (0.58–1.33)	0.77 (0.44–1.32)
Jessa AF knowledge questionnaire	0.67 (0.25–1.84)	2.24 (0.55–9.16)

AF indicates atrial fibrillation; CHA_2DS_2-VASc, congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, stroke or transient ischemic attack, vascular disease, age 65 to 74 years, sex category; OR, odds ratio; and SAGE-AF, Systematic Assessment of Geriatric Elements in Atrial Fibrillation.

*Statistical significance $P<0.05$.

†Some college or less=high school or less; some college. College graduate or more=college graduate; graduate degree.

‡Asian or Pacific Islander, Black, Native American or Alaskan Native, Mixed Race or Hispanic.

Whether patients underestimate or overestimate their bleeding risk, perceptions that differ from predicted bleeding risk may pose a threat to patient safety. OAC therapy is a cornerstone of stroke prevention in atrial fibrillation and is often a lifelong therapy for patients. Patients whose bleeding risk perceptions differ from predicted bleeding risk may be at risk for nonadherence to OAC therapy or lifestyle modifications needed for successful OAC therapy. Additionally, these patients may not be adequately prepared to take an active role in treatment decision making. Given that OACs are the most common cause of adverse drug events in older adults,[23] patient awareness of their bleeding risk would likely reduce harm from these medications. In the present study, we found that most participants underestimated their risk of bleeding. Patients who underestimate their bleeding risk may be more at risk for nonadherence to monitoring activities and lifestyle modifications that are important for anticoagulation success and may not be empowered to take an active role in treatment decision making. There is some evidence to suggest that patients with atrial fibrillation are more concerned with their risk of stroke than their risk of bleeding and are even willing to accept 4 major bleeding events to prevent 1 stroke.[24,25] Less concern for bleeding risk could potentially be related to underestimation of bleeding risk.

Somewhat unexpectedly, atrial fibrillation knowledge did not differ between those who underestimated their risk and those who correctly estimated their risk. The majority of patients who underestimated their risk reported being very knowledgeable or somewhat knowledgeable about their personal bleeding risk. Our results suggest that patients' overall knowledge of their condition may not necessarily correspond with knowledge about their treatment, including their risk of having a major bleeding episode. Our findings suggest that patient education efforts to improve their overall knowledge about atrial fibrillation may not be enough to ensure accurate bleeding risk perceptions. However, improved patient engagement through processes such as shared decision making, which aim to build provider–patient relationships, may be useful in aligning patient bleeding risk perceptions with their predicted risk and thereby reducing the potential for serious adverse drug events from OACs.[26] There is evidence that use of decision aids increases accuracy of risk perceptions compared with usual care.[27] More research is needed to examine the use of decision aids related to bleeding risk perceptions.

We found that Whites, men, participants with a history of bleeding, and those with prior diagnoses of hypertension, stroke, and renal disease had significantly higher odds of underestimating their bleeding risk. Clinicians should consider paying particular attention to these individuals. Further research is needed

to explore the relationship of these characteristics with bleeding risk perceptions and how clinicians might partner with patients to align patient expectations of bleeding risk with predicted risk.[27]

Our study has several strengths, including a sample that is contemporary and diverse with respect to type of OAC use, geographical location, and practice type, enhancing the generalizability of our study. Additionally, study variables were measured using validated tools representing patient-focused and clinical characteristics. Our results should be interpreted with several limitations in mind. The data are cross-sectional and our cohort consisted of mostly White participants, thus limiting our generalizability to non-White patients on OAC therapy and our ability to make meaningful comparisons across ethnicities. Additionally, bleeding risk perceptions were assessed only in participants who were on anticoagulation therapy. As patients who were untreated were not include in the analysis, our findings may be biased toward patients who were less concerned with their bleeding risk. Additionally, among the 1244 SAGE-AF participants at baseline, 147 did not complete year 1 follow-up and among those, 125 participants were on OAC therapy. The average HAS-BLED score of participants who were lost to follow-up was 3.6±1.1 and is significantly higher than participants who completed our year 1 follow-up (3.2±1.1, $P<0.05$). However, given that the average HAS-BLED score of those lost to follow-up is above the HAS-BLED cutoff of 3, it is likely that these participants would have also underestimated their bleeding risk. Another limitation is the absence of a measure for adherence to OAC therapy and lifestyle modifications. Such measures may have shed additional insight on patient's bleeding risk perceptions and how they affect therapy management. Lastly, our measurement of perceived bleeding risk did not have a "I don't know" option. This may have resulted in participants reporting lower perceived risk.[28]

CONCLUSIONS

The results of this study of 754 older men and women with confirmed atrial fibrillation on OAC therapy found that nearly three-quarters of patients underestimated their risk of a major bleeding episode. Because health behaviors, such as adherence to medications and lifestyle changes or treatment decision making, are significantly influenced by patient's appraisal of risks and benefits,[29] it is important that healthcare providers ensure that their patients with atrial fibrillation have a thorough and accurate understanding of their bleeding risk while on OAC therapy. This work adds to the literature regarding the importance of understanding pharmaceutical risk perceptions among patients. More research is needed to understand how patient

pharmaceutical risk perceptions affect patient health behaviors and subsequent outcomes.

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SUPPLEMENTAL MATERIAL

Figure S1. Distribution of Perceived and Predicted Bleeding Risk: The SAGE-AF Study.