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Self-reported risk of stroke and factors associated with underestimation of stroke risk among older adults with atrial fibrillation: the SAGE-AF study

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Abstract

Background Though engaging patients with atrial fibrillation (AF) in understanding their stroke risk is encouraged by guidelines, little is known regarding AF patients' perceived stroke risk or its relationship with oral anticoagulation (OAC) use. We aim to identify factors associated with underestimation of stroke risk among older patients with AF and relate this to OAC use. **Methods** Data are from the ongoing SAGE (Systematic Assessment of Geriatric Elements)-AF study, which included older patients (> 65 years) with non-valvular AF and a CHA_2DS_2-VASc score of ≥ 2. Participants reported their perceived risk of having a stroke without OAC. We compared the perceived risk to CHA_2DS_2-VASc predicted stroke risk and classified participants as "over" or "under" estimators, and identified factors associated with underestimation of risk using multiple logistic regression. **Results** The average CHA_2DS_2-VASc score of 915 participants (average age: 75 years, 47% female, 86% white) was 4.3 ± 1.6, 43% of participants had discordant predicted and self-reported stroke risks. Among the 376 participants at highest risk (CHA_2DS_2-VASc score ≥ 5), 46% of participants underestimated their risk. Older participants (≥ 85 years) were more likely and OAC treated patients less likely to underestimate their risk of developing a future stroke than respective comparison groups. **Conclusions** A significant proportion of study participants misperceived their stroke risk, mostly by overestimating. Almost half of participants at high risk of stroke underestimated their risk, with older patients more likely to do so. Patients on OAC were less likely to underestimate their risk, suggesting that successful efforts to educate patients about their stroke risk may influence treatment choices.

1 Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia and constitutes a global health problem.[1] Approximately 34 million people have AF worldwide, a number expected to double over the next thirty years.[2,3] Cardioembolic stroke is the most serious complication of AF and individuals affected by this arrhythmia have a two to five fold higher risk of stroke compared with individuals free from AF.[4–6]

Embolic strokes from AF are preventable and contem-porary oral anticoagulants (OAC) reduce stroke risk by up to 70%.[7] Since 2011, the CHA_2DS_2-VASc score has been used to predict stroke risk and inform treatment decisions.[8–11] Contemporary guidelines suggest that men with a CHA_2DS_2-VASc score ≥ 2 and women with a CHA_2DS_2-VASc score ≥ 3 are at increased risk for developing a stroke and may benefit from the receipt of OAC;[12] many patients with AF with an elevated CHA_2DS_2-VASc score, however, do not receive OAC.[13] Several factors likely contribute to underuse of OAC compared with guideline recommendations, including the increased risk of bleeding. On the other hand, patient and provider biases about the relative risks versus benefits of OAC treatment for AF may also contribute to this less than optimal treatment of AF, and patient refusal of OAC is commonly cited by healthcare providers as a reason for the withholding of OAC.[14–16] Although several studies have shown that healthcare providers tend to

underestimate their patient's risk of stroke,[17] little is known about how patients with AF perceive their stroke risk, especially among older adults who are at greatest risk for stroke. Moreover, the AF treatment guidelines support shared OAC decision making, and patients with AF should optimally play an active role in their OAC treatment decisions.[18]

Using data from the ongoing SAGE (Systematic Assessment of Geriatric Elements)-AF study, which enrolled older adults with non-valvular AF (NVAF) and a CHA_2DS_2-VASc score ≥ 2,[19,20] we evaluated participants' perceptions of stroke and compared it to their predicted risk of stroke using the CHA_2DS_2-VASc risk score and evaluated factors associated with patient's underestimation of their stroke risk. We hypothesized that underestimation of perceived risk of stroke would be common and would be associated with the receipt of OAC.

2 Methods

2.1 Study population

Details of the SAGE-AF study has been previously described.[19,20] In brief, adults ≥ 65 years with NVAF were recruited between 2015 and 2018 from five medical centers in Massachusetts and Georgia.[19,20] To be included in SAGE-AF study, participants had to: (1) be scheduled for an ambulatory care visit; (2) carry a diagnosis of NVAF detected on electrocardiogram, Holter monitor or listed in the medical record; (3) be aged 65 years or older; and (4) have a CHA_2DS_2-VASc score ≥ 2.[21] Exclusion criteria included: (1) a documented contraindication to OAC therapy (*i.e.*, history of intercranial hemorrhage, mechanical heart valve, end-stage renal disease); (2) OAC intake for an indication other than NVAF; (3) failure to demonstrate adequate intact decision-making capacity for informed consent; (4) scheduled invasive intervention associated with high risk of uncontrollable bleeding; (5) unwillingness for any reason to return for subsequent follow-up visits; or (6) not speaking English, being pregnant, or a prisoner or in custody.

Participants' demographic, clinical, treatment, and laboratory characteristics were abstracted from medical records by trained study staff using standardized methods.[19,20] Information included participants' age, race, sex, stroke risk factors, type of AF, medications, lifestyle practices, relevant medical history, and serum hemoglobin. The CHA_2DS_2-VASc scoring system was used to predict the annual stroke risk in all SAGE-AF participants.[19,20] Participants completed a comprehensive geriatric assessment and structured interview, assessing AF-related quality-of-life,[22] medication adherence, OAC treatment satisfaction, AF knowledge

of stroke risk, depression and anxiety. To assess quality-of-life among SAGE-AF participants, we used the Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) questionnaire.[22] The Anti-Clot Treatment Scale was used to assess participants' satisfaction with their anticoagulation therapy.[23] Perceived efficacy in patient-physician interaction (PEPPI) was used to assess participants' confidence in their physician interactions.[24] Study participants also performed a one-year follow-up examination, including repeat assessments of cognitive and physical function. All eligible participants provided written informed consent prior to formal study enrollment. All study protocols were approved by the Institutional Review Boards at the University of Massachusetts Medical School, Boston University and Mercer University.

2.2 Self-reported risk of stroke

To assess perceived stroke risk, participants were asked at the one-year follow-up examination, "What do you think your annual risk of having a stroke from a clot would be if you were not treated with an anticoagulant?". The response categories included, "no chance (0%)", "low chance (1%–2%)", "medium chance (3%–6%)", "high chance (7%–9%)" and "very high chance (> 10%) of a clot-based stroke in the next year." The first three categories (perceived risk of stroke $\leq 6\%$) corresponded to a CHA_2DS_2-VASc score of 2–4, which is approximately equivalent to a < 6% estimated annual risk of stroke; while the latter two categories (perceived risk of stroke > 6%) corresponded to a CHA_2DS_2-VASc score of ≥ 5, which is approximately equivalent to an estimated annual risk of stroke of $\geq 6\%$.

2.3 Estimated risk of stroke

The CHA_2DS_2-VASc scoring system (congestive heart failure/left ventricular ejection fraction $\leq 40\%$, hypertension, age ≥ 75 years, diabetes mellitus, stroke/transient ischemic attack/thromboembolism history, vascular disease, age: 65–74 years, female sex), collected at baseline, was used to predict the risk of stroke in all study participants.[21] All SAGE-AF participants had a CHA_2DS_2-VASc score ≥ 2. The maximum CHA_2DS_2-VASc score that can be achieved is 9 corresponding to an estimated 15% annual risk of stroke.[21] The CHA_2DS_2-VASc scores of 4 and 5 correspond to 4% and 6.7% estimated annual risk of stroke, respectively.[21] To evaluate underestimation among those at the highest risk for a future stroke, and allow comparison to perceived risk, we grouped participants into those with a CHA_2DS_2-VASc score 2–4 (< 6%) and those with a CHA_2DS_2-VASc score ≥ 5 ($\geq 6\%$).

2.4 Statistical analysis

We grouped participants into those who perceived their stroke risk to be low versus those who perceived their risk to be high and then examined rates of underestimation compared with their CHA_2DS_2-VASc predicted risk. Descriptive statistics were used to evaluate the study participants in terms of baseline characteristics and clinical factors. Among the 376 participants at highest risk of stroke (CHA_2DS_2-VASc score $\geq$ 5), we compared the characteristics of participants who underestimated their stroke risk to those who correctly estimated their risk of stroke risk using the Pearson's chi-square test for categorical variables and the *t*-test for continuous variables. We then used a logistic regression analysis to examine participant factors that were associated with underestimation of stroke risk in the 376 participants with CHA_2DS_2-VASc $\geq$ 5 (an estimated annual risk of $\geq$ 6%). Model building was performed by adjusting for groups of variables based on whether they varied significantly between concordance groups in univariate models and based on their clinical relevance. In regression Model 1, we adjusted for sociodemographic variables, including age, sex, level of education, and provider type. In the more comprehensive regression Model 2, we additionally adjusted for medical history (e.g., history of stroke, history of bleeding, depression, and anxiety), frailty, cognitive impairment, time since AF diagnosis, and patient reported outcomes (knowledge of AF stroke risk, AFEQT, PEPPI, bothered from AF $\geq$ 1 symptom). All statistical analyses were carried out using SAS 9.4 (SAS Institute, Inc., Cary, North Carolina, USA).

3 Results

A total of 1097 SAGE-AF participants were interviewed at the one-year follow-up; among these, 915 participants (83%) had data available on their self-reported stroke risk and were included in the present analysis. Participants were, on average, 75 years old, nearly half (47%) were women, 86% were white, and 45% of participants had at least a college degree. The average CHA_2DS_2-VASc score of study participants was 4.3 ± 1.6. Nearly two-thirds of participants ($n = 559$) had paroxysmal NVAF, 90 participants (10%) had a prior stroke or transient ischemic attack. Most participants ($n = 785$, 86%) were on OAC and approximately half of those treated with OAC were treated with warfarin ($n = 444$).

Overall, 43% of study participants ($n = 390$) exhibited discordance between their self-reported and predicted (based on CHA_2DS_2-VASc) stroke risk (Table 1), with more than one-half of these participants (55%) overestimating their

stroke risk. Among the 539 participants who were in the lower risk group based on their CHA_2DS_2-VASc score (< 6% annual predicted risk for stroke), 60% of participants accurately self-reported their risk of stroke, whereas 40% of participants overestimated their risk. On the other hand, among the 376 participants in the highest risk group based on their CHA_2DS_2-VASc score ($\geq$ 6% annual predicted risk of stroke), 54% of participants ($n = 202$) accurately estimated their risk of stroke and 46% of participants ($n = 174$) underestimated their risk.

Among SAGE-AF participants at highest predicted risk for stroke, those with a higher CHA_2DS_2-VASc score, a history of depression, a self-reported fall in the past six months, a higher AFEQT score, those bothered by $\geq$ 1 AF symptom in the past four weeks, and those who reported a greater burden from OAC were significantly more likely to correctly estimate than to underestimate their risk of stroke. (Table 2)

As shown in Table 3, participants $\geq$ 85 years, compared to those in the youngest age category (65–74 years), were 2.5 times more likely to underestimate than to correctly estimate their risk of a future stroke after adjusting for other sociodemographic and clinical variables (adjusted OR = 2.53, 95% CI: 1.22–5.26). Participants on OAC treatment were 56% less likely to underestimate their risk of stroke than to correctly estimate their risk after adjusting for other potentially confounding variables (adjusted OR = 0.44, 95% CI: 0.21–0.91).

4 Discussion

In this contemporary study of older adults with NVAF, we observed that 43% of study participants either over or underestimated their predicted risk for stroke. Among those at highest risk of stroke, we observed that older patients with NVAF were more likely, and OAC treated patients less likely, to underestimate their risk of a stroke during the coming year.

Few studies have examined self-reported risk of stroke or compared this to the CHA_2DS_2-VASc predicted stroke risk

Table 1. Comparison of perceived risk of stroke versus CHA_2DS_2-VASc estimated risk of stroke: SAGE-AF study.

	CHA_2DS_2-VASc 2–4 (< 6%)	CHA_2DS_2-VASc $\geq$ 5 ($\geq$ 6%)	Total
Perceived risk $\leq$ 6%	323	174[*]	497
Perceived risk > 6%	216	202	418
Total	539	376	915

[*]Refers to under estimators.

Table 2. Baseline characteristics according to the under estimators compared to the correct estimators in the estimated risk group ≥ 6%.

Baseline characteristics	Estimated risk ≥ 6% (n = 376)		
	Correct estimators (n = 202)	Under estimators (n = 174)	P-value
Age, yrs	76.4 ± 6.0	77.8 ± 7.0	0.05
Female	123 (61%)	92 (53%)	0.12
Married	90 (45%)	87 (51%)	0.20
Non-Hispanic white	166 (82%)	143 (83%)	0.90
< College graduate	130 (65%)	113 (66%)	0.78
Time since AF diagnosis, yrs	6.1 ± 4.0	6.0 ± 5.0	0.68
Type of AF			
Paroxysmal	127 (69%)	95 (63%)	0.24
Persistent/Permanent	57 (31%)	56 (37%)	
On OAC treatment	185 (92%)	148 (85%)	0.05
Warfarin	113 (61%)	87 (59%)	0.72
Managed by clinic	77 (68%)	55 (63%)	0.47
Not managed by clinic	36 (32%)	32 (37%)	
Risk scores			
CHA$_2$DS$_2$-VASc	6.0 ± 1.0	5.8 ± 1.0	0.04
HAS-BLED	3.7 ± 1.0	3.6 ± 1.0	0.70
Medical history			
Heart failure	123 (61%)	103 (59%)	0.74
Myocardial infarction	71 (35%)	51 (29%)	0.23
PVD	54 (27%)	46 (26%)	0.95
Hypertension	191 (95%)	168 (97%)	0.35
Diabetes	89 (44%)	72 (41%)	0.60
Major bleeding	55 (27%)	44 (25%)	0.67
Dyslipidemia	164 (81%)	149 (86%)	0.25
Stroke/Transient ischemic attack	47 (23%)	35 (20%)	0.46
Alcohol use	54 (27%)	44 (25%)	0.75
Anemia	90 (45%)	71 (41%)	0.46
Asthma/COPD	62 (31%)	56 (32%)	0.76
Renal failure	80 (40%)	76 (44%)	0.42
Frailty category			0.73
Not frail	43 (21%)	43 (25%)	
Pre-frail	121 (60%)	100 (58%)	
Frail	38 (19%)	31 (18%)	
Cognitive impairment	98 (49%)	82 (47%)	0.79
Social isolation	22 (11%)	17 (10%)	0.72
Depression	72 (36%)	43 (24%)	0.02
Anxiety	53 (26%)	32 (18%)	0.07
Fall in past six months	60 (30%)	36 (21%)	0.05
Current smoker	5 (3%)	6 (4%)	0.46
Provider type			
Internist	7 (4%)	8 (5%)	0.57
Cardiologist	89 (44%)	68 (39%)	
EP specialist	106 (53%)	98 (56%)	
Knowledge of AF stroke risk			
No knowledge	19 (9%)	21 (12%)	0.68
Little-some knowledge	116 (57%)	99 (57%)	
Very knowledgeable	67 (33%)	54 (31%)	
AFEQT score	76.2 ± 19.0	81.6 ± 17.0	< 0.01
Bothered by ≥ 1 AF symptom in the past four weeks	32 (16%)	13 (8%)	0.01
Anticoagulation treatment satisfaction			
Burden score	17.2 ± 6.0	15.5 ± 5.0	< 0.01
Benefit score	10.9 ± 4.0	10.2 ± 4.0	0.09
Confidence in physician interactions (PEPPI ≥ 45)	133 (67%)	114 (69%)	0.60

Data are presented as means ± SD or *n* (%). AF: atrial fibrillation; AFEQT: Atrial Fibrillation Effect on QualiTy-of-life; OAC: oral anticoagulation; PEPPI: perceived efficacy in patient-physician interaction; PVD: peripheral vascular disease.

Table 3. Odds ratios (95% CI) for factors associated with underestimation versus correct estimators in the estimated risk ≥ 6% group (*n* = 376).

Participants' characteristics	Estimated risk ≥ 6%		
	Unadjusted OR (95% CI)	Model 1 OR (95% CI)	Model 2 OR (95% CI)
Age, yrs			
65–74	Reference	Reference	Reference
75–84	1.45 (0.92–2.28)	1.45 (0.92–2.31)	1.64 (0.98–2.74)
85 or older	1.86 (0.97–3.56)	2.09 (1.07–4.05)	2.53 (1.22–5.25)
Sex (female *vs.* male)	0.72 (0.48–1.09)	0.65 (0.43–1.00)	0.77 (0.47–1.26)
Level of education			
≥ College	Reference	Reference	Reference
Some college or less	1.06 (0.69–1.63)	1.14 (0.73–1.79)	1.45 (0.88–2.37)
Provider type			
Internist	Reference	Reference	Reference
Cardiologist	0.67 (0.23–1.93)	0.68 (0.22–2.06)	0.60 (0.18–2.02)
EP specialist	0.81 (0.28–2.31)	0.84 (0.28–2.53)	0.77 (0.23–2.62)
Knowledge of AF stroke risk			
No knowledge	Reference		Reference
Little-some knowledge	0.77 (0.39–1.52)		0.95 (0.44–2.05)
Very knowledgeable	0.73 (0.36–1.49)		0.91 (0.40–2.06)
Medical history			
Stroke	0.83 (0.51–1.36)		0.78 (0.43–1.39)
Bleeding	0.91 (0.57–1.44)		0.74 (0.42–1.32)
Depression	0.59 (0.38–0.93)		0.71 (0.38–1.32)
Anxiety	0.63 (0.39–1.04)		0.95 (0.50–1.82)
Risk scores			
CHA_2DS_2-VASc	0.80 (0.64–0.99)		0.81 (0.62–1.05)
HAS-BLED	0.96 (0.80–1.16)		1.16 (0.89–1.51)
On OAC treatment	0.52 (0.27–1.00)		0.44 (0.21–0.91)
Frailty			
Not frail	Reference		Reference
Frail	0.82 (0.43–1.54)		1.12 (0.49–2.56)
Pre-frail	0.83 (0.50–1.36)		0.92 (0.52–1.61)
Cognitive impairment	0.95 (0.63–1.42)		0.86 (0.53–1.39)
Time since AF diagnosis	0.99 (0.95–1.04)		1.00 (0.96–1.05)
AFEQT score	1.02 (1.01–1.03)		1.02 (0.99–1.03)
Bothered by ≥ 1 AF symptom in the past four weeks	0.43 (0.22–0.85)		0.76 (0.33–1.80)
Confidence in physician interaction (PEPPI ≥ 45)	1.13 (0.72–1.75)		1.13 (0.70–1.85)

Model 1: adjusted for sociodemographic factors (age, sex), level of education and provider type. Model 2: adjusted for variables in Model 1 plus medical history (stroke, bleeding, depression, anxiety), knowledge of risk, risk scores (CHA_2DS_2-VASc and HAS-BLED), on OAC treatment, frailty, cognitive impairment, time since AF diagnosis, AFEQT score, bothered by ≥ 1 AF symptom and PEPPI. AF: atrial fibrillation; AFEQT: Atrial Fibrillation Effect on QualiTy-of-life; CI: confidence interval; OAC: oral anticoagulation; OR: odds ratio; PEPPI: perceived efficacy in patient-physician interaction.

in patients with NVAF. In a small cross-sectional study, 91 patients with newly diagnosed AF (mean age: 73 years) from Austria were asked to characterize their stroke risk as low, intermediate, high, or very high. Approximately two-thirds failed to correctly estimate their stroke risk and over half (57%) underestimated their stroke risk.[25] A second cross-sectional study conducted in the US asked 287 older patients with AF (mean age: 72 years) to characterize their

stroke risk using a numeric scale. The majority of study participants did not correctly estimate their stroke risk, with most participants (53%) overestimating their stroke risk.[26] In contrast to the results of these two smaller cross-sectional studies, most SAGE-AF participants correctly estimated their risk of stroke (57%) and more than one-half of those who exhibited disagreement between self-reported and predicted risk overestimated their risk of developing a stroke.

Differences between our study and these prior investigations could be explained by differences in sample size, care settings, sociodemographic and clinical characteristics of the respective study populations, as well as approach used to assess the patients' self-reported risk of stroke.

In the present study, we not only examined the self-reported risk of stroke among older adults with NVAF, but also the relationship between the estimated and self-reported risk of stroke in a large and contemporary cohort. We assessed the perceived risk of stroke using ordinal variables (qualitative approach) with each of the variables corresponding to a numeric risk estimate (%). This method led to a high completion rate (83%) and was designed to align with predicted risk based on each participant's CHA_2DS_2-VASc score.

In the group at highest risk for stroke, a greater proportion of participants aged 85 years and older were more likely to underestimate their risk of stroke compared with patients 65–74 years old. Despite limited data on this topic, older persons (> 75 years) appear to have lower general knowledge about NVAF compared with younger individuals, which might affect their perceived risk of stroke. In addition, older patients may be more likely to defer to their healthcare provider or be less likely to engage in shared decision making.[27] We also found that study participants who were being treated with an OAC were more likely to be aware of their stroke risk, which suggests that OAC treatment is associated with better AF knowledge and supports the guideline-directed practice of engaging patients in shared decision-making.[18] Shared decision-making and increased patient knowledge about their condition improve patient-centered nature of AF care and may, by extension, decrease patient's risk of a future stroke.[28]

A recent study from a global registry (RE-LY AF) including patients with AF from more than 46 countries highlighted the under-treatment of AF patients at risk for stroke.[29] Among AF patients with guideline indications for the receipt of OAC in the study, only one-third received treatment. Although the introduction of direct OACs has been associated with a slight increase in the proportion of patients with AF eligible for receiving OAC, efforts remain needed to address this treatment gap.[30] Shared decision- making interactions, using an AF Shared Decision-Making Tool, have been shown to improve the quality of the decision-making process, leading to higher patient satisfaction and improved medication adherence.[31] We hypothesize that shared-decision making might address the problem of patient undertreatment, but it requires that patients with AF have knowledge of their underlying disease and stroke risk to engage in meaningful conversations with their healthcare provider.[32]

In the present study, nearly one out of every two partici-

pants underestimated their risk of stroke in the group at highest risk ($\geq$ 6%). Patients' increased knowledge of OAC has been shown to have a positive influence on adherence to oral anticoagulants.[33] We observed that OAC treatment was associated with 56% lower odds of underestimating one's stroke risk, suggesting that better knowledge of their NVAF and its impact on stroke risk may be associated with more optimal treatment. Our findings suggest that efforts, particularly among older individuals with NVAF, are needed to increase AF knowledge of stroke risk to better engage patients and that these efforts may increase guideline-directed use of OAC and reduce the risk of preventable strokes.

4.1 Study strengths and limitations

Our study has several strengths. Participants included in this study are enrolled in a large ongoing, multi-center prospective cohort study of older men and women with confirmed NVAF who are well characterized with respect to self-reported symptoms as well as clinical and geriatric comorbid conditions relevant to the natural history and treatment of NVAF. Our study population includes participants with a high degree of comorbidity, enhancing the generalizability of our study findings. Standardized, validated tools for assessment of patient-reported factors, including AF-related quality-of-life, OAC burden and benefit, and patient-physician trust, were employed, enhancing the generalizability and usefulness of our findings to clinicians. In addition, our brief question to assess participants' perceived risk of stroke was well received. However, the present study has several limitations which must be kept in mind in interpreting our study findings. Based on the cross-sectional observational study design, we cannot determine the directionality of observed associations and cannot make causal inferences. The CHA_2DS_2-VASc risk score was obtained from the study's baseline data, whereas self-reported risk was ascertained from the one-year follow-up interview. In addition, our cohort is comprised mainly of white participants, enrolled largely from ambulatory cardiology clinics, and all study participants were at high risk for stroke.

4.2 Conclusions

Our results suggest that a considerable proportion of older patients with NVAF who are at increased risk of stroke incorrectly perceived their risk of stroke, with the majority overestimating their risk. Among patients at highest risk for stroke, older age was associated with greater likelihood, and treatment with OAC lower likelihood, of underestimating stroke risk. Our findings suggest that educational interventions that increase AF knowledge may help to improve the treatment and outcomes of older adults with NVAF.

Acknowledgments

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