"Bleeding Risk, Physical Functioning, and Non-use of Anticoagulation Among Patients with Stroke and Atrial Fibrillation"

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Abstract

Background: Atrial fibrillation (AF) is common among people with stroke. Anticoagulation medications can be used to manage the deleterious impact of AF after stroke, however may not be prescribed due to concerns about post-stroke falls and decreased functioning. Thus, the purpose of this study was to identify, among people with stroke and AF, predictors of anticoagulation prescription at hospital discharge.

Methods: This is a secondary analysis of a retrospective cohort study of data retrieved via medical records, including: National Institutes of Health Stroke Scale score; Functional Independence Measure (FIM) motor score (motor or physical function); ambulation on 2nd day of hospitalization; Morse Falls Scale (fall risk); and HAS-BLED score (Hypertension; Abnormal renal and liver function; Stroke; Bleeding; Labile INRs; Elderly > 65; and Drugs or alcohol). Data analyses included bivariate comparisons between people with and without anticoagulation at discharge. Logistic-regression modeling was used to assess predictors of discharge anti-coagulation.

Results: There were 334 subjects included in the analyses, average age was 75 years old. Anticoagulation was prescribed at discharge for 235 (70%) of patients. In the adjusted regression analyses, only the FIM motor score (adjusted OR = 1.015, 95%CI 1.001-1.028) and the HAS-BLED score (adjusted OR = 0.36, 95%CI 0.22-0.58) were significantly associated with anticoagulation prescription at discharge.

Conclusion: It appears that in this sample, post-stroke anti-coagulation decisions appear to be made based on clinical factors associated with bleed risk and motor deficits or physical functioning. However, opportunities may exist for improving clinician documentation of specific reasoning for non-anticoagulation prescription.

Key Words: Stroke, falls, anticoagulation, physical function, atrial fibrillation,

Introduction

Atrial fibrillation (AF) is a major modifiable risk factor for stroke. Annually, 60,000 strokes occur in the 2.3 million Americans who have atrial AF,[1] an important and serious combination that should be addressed.[2, 3] AF, and subsequent stroke risk, can be mitigated with the use of anticoagulation medications. Such medications can reduce the risk of stroke by two thirds, but these medications also increase the risk of future bleeding.[3, 4] Guidelines for the management of patients with AF indicate that the appropriate choice of treatment should be guided by the relative risk of stroke and bleeding.[5] The net benefit of anticoagulation for AF has been shown to be greatest among patients with a history of stroke.[6] Having a stroke places patients at intermediate or high risk for future thromboembolic events, thus stroke patients are likely to benefit the most from anticoagulation medications.[6, 7]

A potential barrier to the use of anticoagulation, especially among the elderly or those with impaired physical functioning, is the concern about fall risk. Patients with stroke are at increased risk for falls, with up to 73% falling in the first six-months after stroke.[8] Falls remain common in the chronic post-stroke period[9] and are linked to injuries and need of medical care.[10] Impaired physical functioning and high fall risk may lead clinicians to be uncomfortable in prescribing anticoagulants for AF after stroke, despite the robust evidence supporting its use in the post-stroke population.[11] The objectives of this study were to identify, among Veterans with stroke and AF, predictors of anticoagulation prescription at hospital discharge, particularly examining the role of physical functioning and fall risk.

Methods

Design

This was a secondary analysis of a retrospective cohort of Veterans admitted to Veterans Administration Medical Centers (VAMC) with ischemic stroke (Office of Quality and Performance Stroke Special Study (OQP)).[12] We utilized these data to assess the association

between patient fall risk and physical functioning with anticoagulation medication prescription at time of hospital discharge.

Study Population

For the original OQP Stroke Special Project, a cohort of Veterans was assembled using administrative data to identify patients with ischemic stroke based on a high sensitivity algorithm using International Classification of Disease-9 codes. A sample of 5000 patients was obtained by including 100% of Veterans from small volume centers (≤55 patients) and a random sample of 80% of Veterans at high volume centers (>55 patients). Patients were excluded if admitted: for elective carotid endarterectomy; only for post-stroke rehabilitation; for a non-stroke condition when the ischemic stroke event occurred; or to a VAMC that did not use the VHA electronic medical record system.

Data were obtained via electronic medical record abstraction. The data collection tool was designed and revised and pilot tested in collaboration with the senior chart reviewers over a period of several months. Whenever possible, data elements for this study were defined to be identical to items collected as part of the External Peer Review Program to ensure high quality of data collection (e.g., methods for collecting: demographics; medications; laboratory data; etc). Specific training for the record abstraction for this study was developed and implemented using successful approaches deployed in a prior retrospective cohort study and included training models specific to the unique data elements that were collected in this study (e.g., the retrospective NIH stroke scale [NIHSS]).

For this analysis, we included (Figure 1) Veterans with stroke and AF (n=635) who: were classified as being eligible for anticoagulation prescription for AF at discharge (n=447), and who had a documented inpatient fall risk score (Morse Falls Scale, see below); the final sample was n=334.

Potential Predictors of Anticoagulation

Patient level data obtained from medical record review included: demographics, medical comorbidities (including past medical history, the Charlson comorbidity index, as well as concomitant medical conditions present upon admission); stroke symptom characteristics; vital sign data; ambulation status (at hospital day 2 and at discharge); and discharge disposition (categorized as home or not home). Among the 307 abstracted data elements, 90% had an inter-observer agreement ≥70%.[12, 13]

Fall Risk

We used the Morse Falls Scale (Morse) to determine fall risk, commonly used for in-hospital fall risk assessment.[14-16] The Morse-score was abstracted as part of the medical record review. The Morse was part of the nursing admission assessment at the majority of VA hospitals and therefore was routinely collected for most patients. Therefore, missing Morse-scores were related to facility policies regarding nursing admission processes. The Morse includes the following domains: falls history; secondary diagnoses; ambulation aides; intravenous therapy; gait impairment; and mental status. We used the Morse score as a continuous variable in the analyses; higher scores represent higher fall risk; we also classified the Morse score into three categories: <25, low risk; 25-45, moderate risk; and >45 high risk.[17]

Motor Function

We used the reliable and valid motor component of the Functional Independence Measure (FIM) as a measure of motor functioning after stroke.[18, 19] FIM-motor data were available for 271 of patients in this sample. Higher scores represent better functioning and greater independence.

Stroke Severity

We used valid and reliable retrospective National Institutes of Health Stroke Scale (NIHSS) to assess stroke severity.[20, 21] The NIHSS is an 11-item scale and includes: consciousness; vision; language; sensory; ataxia; and arm and leg motor function. Increasing scores represent greater stroke severity.

Thromboembolic Risk

We calculated two scores for use in evaluating the anticoagulation management: the $CHADS_2$ and the HAS-BLED.

The $CHADS_2$ score assesses the following domains: **C**ongestive heart failure (1 point); **H**ypertension (1 point); **A**ge >75 (1 point); **D**iabetes (1 point); and **S**troke or TIA (2 points). The $CHADS_2$ is a commonly used prediction rule for estimation of thromboembolic risk among patients with atrial-fibrillation.[22, 23] A $CHADS_2$ score of >2 indicates increased thromboembolic risk and such patients are recommended for consideration for anticoagulation.[24] Because all of the patients in this study had a stroke, each had a score of at least two, and therefore were considered at moderate to high thromboembolic risk and anticoagulation would have been recommended for all such patients unless a contraindication existed (see below regarding contraindications).

We also calculated a HAS-BLED score, a scale that rates bleeding risk;[25] the HAS-BLED scoring includes a point for: **H**ypertension; **A**bnormal renal and liver function; **S**troke; **B**leeding; **L**abile INRs; **E**lderly age over 65; and **D**rugs or alcohol, including antiplatelet agents and nonsteroidal anti-inflammatory drugs. A HAS-BLED score ≥3 indicates a high risk of bleeding and anticoagulation is cautioned for such patients. Although the HAS-BLED score can range from zero to nine, the maximum score in this cohort was eight because we did not have data regarding concomitant alcohol and drug use.

Outcome Measure – Anticoagulation

Veterans eligible for anticoagulation were identified via an algorithm similar to that which is used by the Joint Commission, developed to identify patients who were ideal candidates for antithrombotic therapy (yes or no). Patients were not considered appropriate for anticoagulation at discharge if they: had a code status of comfort-care only; were discharged to hospice care; were discharged to other inpatient care; left against medical advice; were discharged to a Critical Access Hospital; were expired; the patient refused anticoagulation; or if there was any documented contraindication to anticoagulation or reason for non-prescription of anticoagulation. Documentation of a contraindication for anticoagulation or other reason for a lack of anticoagulation was a specific item in the algorithm (yes or no 'document a contraindication/reason for not prescribing an anticoagulant medication at discharge', not applicable, or patient refusal). Examples of reasons for not prescribing antithrombotic therapy included but were not limited to: allergy to antithrombotic therapy; current aortic dissection; bleeding disorder; brain/CNS cancer; CVA/hemorrhage; extensive/metastatic cancer; hemorrhage, any type; intracranial surgery/biopsy; peptic ulcer, current; planned surgery within 7 days of discharge; risk or bleeding, current; unrepaired intracranial aneurysm. Anticoagulation for AF included warfarin, low molecular weight heparin, alternative anticoagulants, or intravenous heparin. Inter-rater agreement for all of the variables related to anticoagulation at discharge was 89% or higher.

Statistical Analysis

All analyses were completed using SAS statistical software (version 9.2© (Cary, NC). Stroke characteristics, demographics, fall risk, and physical functioning variables potentially influencing anticoagulation medication prescription were evaluated in bivariate tests using chi-square, Fisher's exact, one way analysis of variance, or the Wilcoxon rank-sum test.

To identify variables independently associated with anticoagulation, we constructed bivariate and multivariable logistic regression models estimated with generalized estimating equation methodology which allowed us to incorporate clustering of patients within hospitals. The outcome of interest was anticoagulation medication prescription at discharge. Independent variables were those statistically significant at <0.05 in the bivariate tests and factors identified via *a priori* clinical judgment (Morse; FIM-motor; day 2 ambulation; NIHSS; and discharge HAS-BLED$\geq$3). An event-per-variable ratio of 10:1 was maintained in multivariable models.[26, 27] The level of statistical significance was set at p<0.05. No imputations were made for missing data.

Results

The baseline characteristics for the 334 subjects included in this analysis are presented in Table 1. The average age was 75 years (±10), 328 (98%) were male, and 239 (77%) were white.

At discharge, anticoagulation was prescribed for 235 (70%) of patients; 230 patients were prescribed warfarin, 28 patients were prescribed a non-warfarin anticoagulant medication, most commonly in combination with warfarin (e.g., 24 patients with low molecular weight heparin and warfarin). A total of 98/334 (29%) patients were taking warfarin or a non-warfarin anticoagulant at hospital admission: 93/235 (40%) of patients discharged on any anticoagulant were taking an anticoagulant upon admission (Table 1).

Patients not prescribed anticoagulation had decreased function as per the FIM-motor (42 vs 53, p=0.003), had worse Morse-scores (59 vs 52, p=0.009), and were less likely to be ambulatory (day 2 of hospitalization 60% vs 74%, p=0.009 or discharge (69% vs 80%, p=0.020). Patients discharged without anticoagulation were at greater bleeding risk (HAS-BLED, 4 vs. 3, p<0.001; Table 1).

We included NIHSS, FIM-motor, ambulation on day 2 of hospitalization, Morse-score, and HAS-BLED in the multivariable model. Only FIM-motor scores (adjusted OR=1.02, 95%CI

1.001 to 1.028, p=0.03) and HAS-BLED scores (adjusted OR=0.36, 95%CI 0.22 to 0.58),

p<0.001) were significantly associated with anticoagulation prescription at discharge. All

independent variables were centered at their means (FIM=51.8 and HAS-BLED=3.45).

Therefore, for the FIM-motor, there was a 2% increase in the odds of being prescribed

anticoagulation at discharge for every one unit of increase in FIM-motor greater than 51.8. The

HAS-BLED had the largest effect; for every unit increase above the mean of 3.45 there was a

64% reduction in the likelihood of receiving an anticoagulation prescription at discharge.

Discussion

The efficacy of anticoagulation medication use in prevention of stroke and stroke related

death has been well documented.[28-33] However, due to concerns about intracranial hemorrhage

and systemic bleeding, not all patients at risk for stroke with AF are prescribed anticoagulation

medications.[29] Clinicians likely consider post-stroke fall risk, motor functioning, stroke events,

hypertension, and other variables when evaluating the benefit-to-risk ratio for individual patients.

Overall, we found the majority (70%) of eligible patients with stroke and AF were

prescribed anticoagulation at hospital discharge. This rate is somewhat lower than the

anticoagulation rate observed in hospitals participating in the American Stroke Association Get

With The Guidelines-Stroke program, where rates improved from 60% in 2003 to >90% by

2009.[34] It is expected that the rate would be somewhat lower in our sample, as it was not

restricted to hospitals participating in stroke quality improvement programs.

The 30% of eligible patients who were not prescribed an anticoagulant at discharge had

worse FIM-motor scores, worse Morse-scores, and were less likely to be ambulatory on day 2 of

the hospitalization or at discharge. Thus, patient physical functioning may be playing a key role

in anticoagulation decision-making. Importantly, 70% of this study sample were receiving

appropriate anticoagulation. The other 30% did not receive anticoagulation; however it may

have been appropriate for these individuals to not receive anticoagulation, but there is a lack of

documentation regarding the decision-making. Our date does not include the actual documented contraindication, only 'yes or no', whether or not a contraindication was documented. It is unknown whether the contraindication would or would not be appropriate to withhold anticoagulation, thus the risk-to-benefit ratio of anticoagulation cannot be assessed. Of additional note, an important future area of quality improvement work should target the documentation of clinical decision-making relevant to anticoagulation.

Our results indicate that only FIM-motor scores and the discharge HAS-BLED score were independent predictors of anticoagulation at post-stroke discharge. We hypothesized that fall risk would be predictive of anticoagulation prescription post-stroke, but our results did not support this hypothesis, at least independently. Our bivariate results demonstrated a significant difference in Morse-scores between those with and those without anticoagulation prescription; however the Morse was not maintained in the regression model. Additionally, it is of interest that stroke severity did not appear to influence anticoagulation decision-making in these patients, even though stroke risk is a primary indicator for anticoagulation.[5]

The FIM-motor score was maintained in the model. Perhaps this is because the FIM-motor score encompasses motor disability, including transfers, stairs, and locomotion, and thus fall risk is embedded. Similarly, although the NIHSS (a measure of stroke severity) was entered into the multivariable analysis, it was not retained in the final model; we hypothesize that the FIM-motor component accounted for disability related to neurological symptoms. Therefore, while it seems that management of AF may improve functional recovery,[35] physicians may be wary of prescribing or managing anticoagulation for someone with decreased motor ability.

Interestingly, the HAS-BLED was maintained in the regression analyses, indicating bleeding risk is a predictor of anticoagulation for people with stroke and AF. The CHADS$_2$ was likely not different between groups because all of the patients scored at least a 2 due to the stroke event for which they were admitted to the hospital. Those who did not receive anticoagulation had an average of a 4 on the HAS-BLED; as stated above, a score of ≥3

indicates a high risk for bleeding and such patients are not recommended for receipt of anticoagulation therapy. Our findings regarding the HAS-BLED are interesting when couched in a review of pertinent literature and AF guidelines. The HAS-BLED was recently found to better predict clinically relevant bleeding in people with AF when compared to two other assessments; however all three assessments only performed modestly in predicting bleeding risk.[36] Additionally, the guidelines distributed by the American College of Chest Physicians do not endorse the use of the HAS-BLED to assist in anticoagulation decision-making.[37] Perhaps our finding that the HAS-BLED score was maintained in the predictive model is attributable to this being a study population including people with AF and stroke, the mentioned guidelines include people with AF, not necessarily with stroke. Perhaps an assessment of elevated bleeding risk explains why anticoagulation was not prescribed in this group of patients; however, no documentation about such a bleeding risk assessment was present in the inpatient medical record. Given the robust literature supporting the use of anticoagulation among the post-stroke population with AF, it is necessary to document reasons for not prescribing anti-coagulation medications at the time of hospital discharge.

Limitations

Limitations to this study include that all patients were Veterans (mostly men) cared for in VAMCs across the country; however, this does help us understand care within the single largest healthcare organization in the United States. Given that VHA uses an electronic medical record system but one that does not generally include decision support for AF patients, these results may not be generalizable to systems without electronic medical records or to settings with documentation reminders (or other decision support) related to anticoagulation decision-making or AF management. Finally, the VHA formulary during the study period did not include any of the new anticoagulant medications, and therefore these results pertain mainly to the use of warfarin.

Conclusion

These data suggest that decisions regarding anti-coagulation for Veterans with stroke and AF appear to be made based on Veteran functional disability and bleeding risk. Thus it is likely that some patients are receiving the appropriate care but fail the anti-coagulation measure due to lack of documentation. Clinicians appear to be considering both bleeding risk and motor functioning when making anticoagulation decisions. Clinicians should strive to ensure that medical record documentation specifies reasons and clinical decision-making for non-prescription of anticoagulation for post-stroke patients with AF whom they deem to be poor candidates for anticoagulation.

Funding

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Table 1: Descriptive Statistics for Patients with Atrial Fibrillation and Morse Score by Anticoagulation Status

Variable	Overall	No Anticoagulation at Discharge	Anticoagulation at Discharge	p-value
	(N=334)	(N=99)	(N=235)	
Age, in years (mean ± standard deviation)	75 ± 10	75 ± 10	74 ± 10	0.4402
Sex, male	328 (98%)	97(98%)	231(98%)	0.9999
White race/ethnicity	239 (77%)	67(68%))	172(73%)	0.3076
NIHSS Stroke severity	5 ± 6	5 ± 7	4 ± 6	0.0670
FIM motor (last inpatient assessment)	50 ± 27	42± 26	53 ± 26	**0.0027**
Charlson comorbidity score	2 ± 2	1 ± 2	1 ± 1	0.7144
Comorbidities, past history of:				
Atrial Fibrillation	334 (100%)	99(100%)	235(100%)	
Hypertension	286 (86%)	88(89%)	198(84%)	0.2703
Coronary Artery Disease	122 (36%)	33(33%)	89(38%)	0.4314
Cerebrovascular Disease	107 (32%)	32(32%)	75(32%)	0.9418
Ischemic Stroke	78 (23%)	22(22%)	56(24%)	0.7512
Myocardial Infarction	46 (14%)	16(16%)	30(13%)	0.4109
Transient Ischemic Attack	33 (10%)	11(11%)	22(9%)	0.6246
Hemorrhagic stroke	10 (3%)	4(4%)	6(2%)	0.4904
CEA/Stent procedure	10 (3%)	2(2%)	8(3%)	0.7292
DVT/PE	6 (2%)	0(0%)	6(3%)	0.1849
$CHADS_2$ score at D/C (Mean ± SD)	4 ± 1	4 ± 1	4 ± 1	0.4387
HAS-BLED score at D/C (Mean ± SD)	3 ± 1	4 ± 1	3 ± 1	**<.0001**
Morse falls score	54 ± 25	59 ± 24	52 ± 25	**0.0093**
Discharge disposition to home	190 (57%)	50(50%)	140 (60%)	0.1264
Preadmission independent ambulation	311 (93%)	90(92%)	221(95%)	0.2227

Variable	Overall	No Anticoagulation at Discharge	Anticoagulation at Discharge	p-value
	(N=334)	(N=99)	(N=235)	
Hospital Day 2 independent ambulation	227 (68%)	56(60%)	171(74%)	**0.0084**
Discharge independent ambulation	257 (77%)	68(69%)	189(80%)	**0.0200**
ADMISSION ANTITHROMBOTIC USE				
Any anti-thrombotic	98 (29%)	5 (5%)	93 (40%)	**<.0001**
Non-Warfarin	1 (0.3%)	0	1 (0.43%)	0.7045
Warfarin	98 (29%)	5 (5%)	93 (40%)	**<.0001**

NIHSS=NIH Stroke Scale; FIM=Functional Independence Measure; DVT/PE=Deep vein thrombosis/Pulmonary embolism; CHADS$_2$= **C**ongestive heart failure, **H**ypertension, **A**ge >75, **D**iabetes, and **S**troke or TIA; HAS-BLED=**H**ypertension, **A**bnormal renal and liver function, **S**troke, **B**leeding, **L**abile INRs, **E**lderly age over 65, and **D**rugs or alcohol

Table 2: Predictors of anticoagulation use at discharge, bivariate and multivariable odds ratios and 95% confidence intervals from logistic models with within hospital adjustment

	Bivariate Results				Multivariable Results			
	Estimate (SE)	p-value	Unadjusted Odds Ratios	95% CI	Estimate (SE)	p-value	Adjusted Odds Ratios	95% CI
Intercept					1.739 (0.393)			
NIHSS	-0.035 (0.019)	0.0672	0.965	(0.929, 1.003)	0.0008 (0.023)	0.9730	1.001	(0.956, 1.048)
FIM motor	0.017 (0.005)	0.0004	1.017	(1.008, 1.027)	0.015 (0.007)	0.0329	1.015	(1.001, 1.028)
HAS-BLED score	-0.768 (0.178)	<.0001	0.464	(0.327, 0.657)	-1.033 (0.251)	<.0001	0.356	(0.218, 0.582)
Morse falls score	-0.014 (0.004)	0.0017	0.986	(0.978, 0.995)	-0.006 (0.006)	0.3689	0.994	(0.982, 1.007)
Hospital Day 2 independent ambulation	0.675 (0.256)	0.0085	1.963	(1.188, 3.245)	0.115 (0.395)	0.7709	1.122	(0.557, 2.433)

NIHSS=NIH Stroke Scale; FIM=Functional Independence Measure; DVT/PE=Deep vein thrombosis/Pulmonary embolism; CHADS$_2$= Congestive heart failure, Hypertension, Age >75, Diabetes, and Stroke or TIA; HAS-BLED=Hypertension, Abnormal renal and liver function, Stroke, Bleeding, Labile INRs, Elderly age over 65, and Drugs or alcohol

List of abbreviations

- Atrial fibrillation (A-fib)

- Veterans Administration Medical Centers (VAMC)

- Veteran Health Administration (VHA)

- Office of Quality and Performance Stroke Special Study (OQP)

- External Peer Review Program (EPRP)

- National Institutes of Health Stroke Scale (NIHSS)

- Functional Independence Measure (FIM)

- **C**ongestive heart failure; **H**ypertension; **A**ge >75; **D**iabetes; and **S**troke or TIA (CHADS$_2$)

- **H**ypertension; **A**bnormal renal and liver function; **S**troke; **B**leeding; **L**abile INRs; **E**lderly age over 65; and **D**rugs or alcohol (HAS-BLED)

Figure 1. Eligibility Flow Diagram

| Ischemic stroke patients (N=3931) | → | No history of atrial fibrillation or atrial fibrillation observed (N=3296) |

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| Ischemic stroke patients with atrial fibrillation (N=635) | → | In-hospital death (N=49) |

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| Ischemic stroke patients with atrial fibrillation discharged alive (N=586) | → | Comfort measures only, discharge to hospice or acute care hospital, or left against medical advice (N=30) |

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| Ischemic stroke patients with atrial fibrillation potentially eligible for anticoagulation (N=556) | → | Documentation of reason for no anticoagulation Patient refused (N=6) Contraindication (N=103) |

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| Ischemic stroke patients with atrial fibrillation eligible for anticoagulation (N=447) | → | No Morse Fall Score (N=113) |

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Ischemic stroke patients with atrial fibrillation, eligible for anticoagulation with Morse Fall Score (N=334)