

WARFARIN USE IN PATIENTS WITH ATRIAL FIBRILLATION: IS THERE A DISPARITY IN CARE AMONG PATIENTS MANAGED BY ATTENDING PHYSICIANS COMPARED TO RESIDENTS?

A. Study Purpose and Rationale:

Atrial fibrillation (AF) is a common diagnosis affecting more than 2 million adults in the United States¹. The prevalence of this arrhythmia is on the rise and continues to be a growing public health concern as it is associated with an increased risk of stroke and thromboembolic events. AF is an independent risk factor for stroke and can increase the annual risk by fivefold and may account for up to 15% of all strokes in the US. Anti-coagulation with warfarin has been shown to reduce the risk of ischemic stroke in patients with AF by two-thirds². However, warfarin has also been associated with adverse outcomes including fatal hemorrhage that may outweigh the benefits of anti-coagulation therapy². The American College of Cardiology/American Heart Association/European Society of Cardiology have established guidelines to help identify those patients with atrial fibrillation who may benefit from anti-coagulation. These guidelines clearly recommend anticoagulation therapy for AF patients with stroke risk factors without obvious contraindications³. Despite these recommendations and evidence of efficacy, studies have suggested that the use of warfarin in an outpatient setting remains sub-optimal. Among AF patients with no apparent contraindications, only 40-55% actually receive warfarin⁴⁻⁸. There is an increase in adverse outcomes including death and hospitalization for an ischemic event in those patients determined to be ideal anti-coagulation candidates yet not on anti-coagulation therapy⁷.

The aim of this study is to examine warfarin use in patients with atrial fibrillation cared for in an academic internal medicine clinic by either an attending physician or a medicine resident. More specifically, the study would determine if there is a difference in warfarin use between attending physicians and residents indicating a possible disparity in care. Do medicine residents prescribe appropriate warfarin use more often, the same, or less often than medicine attendings? How does resident and attending warfarin use in this clinic setting compare to warfarin use in other published studies?

Given that ideal anti-coagulation candidates not on anti-coagulation therapy are at an increased risk of adverse outcomes⁷, if a difference in warfarin use for thromboembolic prophylaxis is unmasked between attendings and residents, the clinic may benefit from further investigation and/or intervention to ensure that warfarin is appropriately prescribed to improve outcomes for the clinic population with atrial fibrillation. Also, the

overall incidence of warfarin use in this clinic setting compared to other larger, national studies may provide a measure of quality of care to compare this clinic to other outpatient settings in the United States.

B. Study Design and Statistical Analysis

The study will be a Cross-Sectional Analysis.

The study population will consist of all patients with a known diagnosis of atrial fibrillation treated in the Associates of Internal Medicine Clinic (AIM) at CUMC as determined by ICD9 code 427.31 documented in the EMR. Diagnosis will be confirmed with electronic ECG stored in the EMR demonstrating atrial fibrillation and/or clear documentation of atrial fibrillation in the primary provider's note(s).

The number of subjects to be enrolled is estimated at 600. This estimate is based on 2007 epidemiological data collected about the AIM Clinic's patient population. Per Yuh-Jer Shen et al.⁹, the overall prevalence of atrial fibrillation among a large, diverse cohort of patients aged 60 or older is 5.3%. The prevalence of atrial fibrillation among different ethnicities was estimated to be 8% among Whites, 3.8% among Blacks, and 3.6% among Hispanics. According to AIM Clinic 2007 demographic data¹⁰, the AIM Clinic's total patient panel was 14,000 with an average age of 56. Of these patients, 6% were White, 25% were Black, 59% were Hispanic, and 10% were Other. Based on the predicated prevalence of atrial fibrillation among different ethnicities per Yuh-Jer Shen et al., the estimated number of AIM Clinic patients with atrial fibrillation would be 600.

Patients with a documented diagnosis of atrial fibrillation will be reviewed to determine level of current primary provider (resident vs. attending). In the AIM Clinic, residents care for approximately two-thirds of patients and attendings care for one-third of patients. Patient assignment to either an attending or resident is arbitrary. Based on an estimation of 600 patients with atrial fibrillation, approximately 400 patients will be cared for by residents and approximately 200 patients will be cared for by attendings.

Warfarin use will be determined by existence of INR levels in the EMR, documentation of warfarin use in the provider's note, and/or presence of documentation from AIM Coumadin Clinic. The proportion of appropriate warfarin use among the medicine attendings is assumed to be equivalent to larger national studies of 40-55% (45%)⁴⁻⁸.

To determine appropriate warfarin candidates, the charts of the AF patients will be reviewed to determine warfarin contraindications and indications based on recommendations from the American College of Cardiology/American Heart Association/European Society of Cardiology 2006 guidelines³. Contraindications include previous severe bleeds, presumed poor compliance (dementia, psychiatric illness, substance abuse), frequent falls, severe liver disease, cancer with an increased risk of bleed, recent trauma or surgical procedure. Indications include hypertension,

diabetes mellitus, heart failure, previous stroke or transient ischemic attack, ischemic heart disease, or valvular disease.

Power Analysis was performed to determine effect. To be considered significant, the proportion of warfarin use among residents must be <0.34 or >0.56 for a p-value of 0.1, a power of 80%, an attending group number of 200, a resident group number of 400, and an assumed proportion of warfarin use equal to 0.45 among the attending physicians (determined by prior prevalence studies). Therefore, based on the estimated size of the study population, warfarin use among residents will be statistically different from attendings if less than 34% or greater than 56% of atrial fibrillation patients cared for by residents are prescribed warfarin assuming that warfarin use among attendings is consistent with the prevalence of use among physicians examined in national studies at 45%.

Data will be collected for each current patient in the AIM clinic with a diagnosis of Atrial Fibrillation. Proportion of warfarin use among patients cared for by residents will be compared to the proportion of warfarin use among patients cared for by attendings using a Chi Square analysis to determine statistical significance.

Epidemiological data will also be collected for each current patient in the AIM clinic with a diagnosis of Atrial Fibrillation including age, race, and gender.

C. Study Procedure

Non-Applicable.

D. Study Drugs

Non-Applicable.

E. Medical Device

Non-Applicable.

F. Study Questionnaire

Non-Applicable.

G. Study Subjects

The study population will include all patients with a known diagnosis of atrial fibrillation currently being treated in the Associates of Internal Medicine Clinic (AIM) at CUMC.

Inclusion criteria includes:

- patient must have documented diagnosis of atrial fibrillation per ICD9 code 427.31
- patient must have been seen in the AIM Clinic by a physician between January 2010 to January 2011.

Exclusion criteria includes:

- an inability to confirm ICD9 code diagnosis of atrial fibrillation with an ECG in the electronic database or documentation of atrial fibrillation in the primary provider's note(s)
- an inability to identify if the primary AIM clinic provider is a resident or an attending
- patient was seen only once by a physician in the AIM Clinic with no follow-up appointments

H. Recruitment of Subjects

Non-Applicable.

I. Confidentiality of Study Data

All information will be obtained in a computerized database accessible only to investigators. Patients included in the cross sectional analysis will be assigned a study number to protect their identity. All study subject identifying data will be destroyed when the study is completed.

J. Potential Conflicts of Interest

There are no potential conflicts of interest associated with this study.

K. Location of the Study

Associates of Internal Medicine Clinic at CUMC. Only data from the EMR will need to be collected.

L. Potential Risks

No risks to patients are associated with this study. This is purely a data analysis study involving information already included in the EMR.

M. Potential Benefits

There will be no direct benefit to study patients included in the cross sectional analysis. The study may benefit future or current patients by improving management of atrial fibrillation through increased recognition of under utilization of warfarin in the AF clinic population by attendings and/or residents with the goal of increasing appropriate warfarin use to prevent adverse outcomes.

N. Alternative Therapies

Non-Applicable.

O. Compensation to Subjects

Non-Applicable.

P. Costs to Subjects

Non-Applicable.

References

1. SS Chugh, JL Blackshear, WK Shen, SC Hammill, BJ Gersh. Epidemiology and natural history of atrial fibrillation: clinical implications. *J Am Coll Cardiol.* 2001;37:371-378.
2. Atrial Fibrillation Investigators. Atrial fibrillation: risk factors for embolization and efficacy of antithrombotic therapy. *Arch Intern Med.* 1994;154:1449-1457.
3. V Fuster, LE Ryden, RW Asinger, et al. ACC/AHA/ESC guidelines for the management of patients with atrial fibrillation: executive summary. A report of the ACC/AHA task force on practice guidelines (writing committee to revise the 2001 guidelines for the management of patients with atrial fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Circulation.* 2006;114:700-752.
4. Tammy J. Bungard, William A. Ghali, Koon K. Teo, Finlay A. McAlister, Ross T. Tsuyuki. Why do Patients with Atrial Fibrillation Not Receive Warfarin? *Arch Intern Med.* 2000;160:41-46.
5. Randall S. Stafford and Daniel E. Singer. Recent National Patterns of Warfarin Use in Atrial Fibrillation. *Circulation.* 1998;97:1231-1233.
6. Alan S. Go, Elaine M. Hylek, Lelia H. Borowsky et al. Warfarin Use among Ambulatory Patients with Nonvalvular Atrial Fibrillation: the Anticoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. *Ann Intern Med.* 1999;131:927-934.
7. Brian F. Gage, Michael Boechler, Amy L. Doggett, Gary Fortune, Greg C. Flaker, Michael W. Rich and Martha J. Radford. Adverse Outcomes and Predictors of Underuse of Antithrombotic Therapy in Medicare Beneficiaries with Chronic Atrial Fibrillation. *Stroke.* 2000;31:822-827.
8. Leif Friberg, Niklas Hammar, Mattias Ringh, Hans Pettersson, and Marten Rosenqvist. Stroke prophylaxis in atrial fibrillation: who gets it and who does not? *European Heart Journal.* 2006;27:1954-1964.
9. Albert Yuh-Jer Shen, Richard Contreras, Serap Sobnosky et al. Racial/Ethnic Differences in the Prevalence of Atrial Fibrillation Among Older Adults – A Cross Sectional Study. *Jour Nat Med Assoc.* 2010;102:906-913.
10. Chang, Nancy. "Re: AIM Demographics." Email to Rose Tompkins. 14 February, 2011.