ORIGINAL RESEARCH

Anticoagulant Use for Prevention of Stroke in a Commercial Population with Atrial Fibrillation

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Background: Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, and patients with AF are at an increased risk for stroke. Thromboprophylaxis with vitamin K antagonists reduces the annual incidence of stroke by approximately 60%, but appropriate thromboprophylaxis is prescribed for only approximately 50% of eligible patients. Health plans may help to improve quality of care for patients with AF by analyzing claims data for care improvement opportunities.

Objectives: To analyze pharmacy and medical claims data from a large integrated commercial database to determine the risk for stroke and the appropriateness of anticoagulant use based on guideline recommendations for patients with AF.



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Disclosures are at end of text

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Methods: This descriptive, retrospective claims data analysis used the Anticoagulant Quality Improvement Analyzer software, which was designed to analyze health plan data. The data for this study were obtained from a 10% randomly selected sample from the PharMetrics Integrated Database. This 10% sample resulted in almost 26,000 patients with AF who met the inclusion criteria for this study. Patients with a new or existing diagnosis of AF between July 2008 and June 2010 who were aged ≥18 years were included in this analysis. The follow-up period was 1 year. Demographics, stroke risk level (CHADS₂ and CHA₂DS₂-VASc scores), anticoagulant use, and inpatient stroke hospitalizations were analyzed through the analyzer software.

Results: Of the 25,710 patients with AF (CHADS₂ score 0-6) who were eligible to be included in this study, 9093 (35%) received vitamin K antagonists and 16,617 (65%) did not receive any anticoagulant. Of the patients at high risk for stroke, as predicted by CHADS₂, 39% received an anticoagulant medication. The rates of patients receiving anticoagulant medication varied by age-group—16% of patients aged <65 years, 22% of those aged 65 to 74 years, and 61% of elderly ≥75 years. Among patients hospitalized for stroke, only 28% were treated with an anticoagulant agent in the outpatient setting before admission.

Conclusions: Our findings support the current literature, indicating that many patients with AF are not receiving appropriate thromboprophylaxis to counter their risk for stroke. Increased use of appropriate anticoagulation, particularly in high-risk patients, has the potential to reduce the incidence of stroke along with associated fatalities and morbidities.

trial fibrillation (AF) is the most common clinically significant cardiac arrhythmia, diagnosed in approximately 1% of the general population.¹ It is estimated that AF currently affects more than 2 million people in the United States and more than 4 million across the European Union, with the number of US patients with AF estimated to increase 2.5-fold by the year 2050.¹²

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KEY POINTS

- Atrial fibrillation (AF) is responsible for approximately 20% of all strokes; stroke is the third most common cause of US deaths.
- Current guidelines for stroke prevention recommend thromboprophylaxis for all patients with AF who are at high risk for stroke.
- Appropriate thromboprophylaxis is the mainstay of stroke prevention, resulting in approximately 60% ischemic stroke risk reduction.
- ➤ In this claims data analysis, however, 65% of patients with AF did not have claims for anticoagulant therapy; the rate was only slightly lower (61%) among patients at high risk for stroke, with only 39% receiving anticoagulation therapy.
- ➤ Age played some role in the rate of anticoagulation use: only 16% of patients with AF under age 65 years had claims for an anticoagulant agent compared with 22% for those aged 65 to 74 years and 61% among those aged ≥75 years.
- These findings echo previous findings in the medical literature, suggesting a significant underutilization of anticoagulation therapy in people with AF.
- Although the cost of treating AF is significant amounting to an estimated \$6.65 billion direct cost in 2005—this amount is dwarfed by the treatment of stroke, which in 2010 was estimated at \$73.7 billion for direct and indirect costs.
- Quality of care in this patient population can be improved by using software designed to analyze claims data to identify practice patterns and ways to improve treatment adherence.

AF is a powerful independent risk factor for stroke. Patients with AF are estimated to have a 5-fold greater risk for stroke than those without AF,³ and AF is thought to have a causative role in approximately 20% of all strokes.⁴ The individual stroke risk may be estimated using the CHADS₂ (C = congestive heart failure, H = hypertension, A = age, D = diabetes, and S₂ = stroke/transient ischemic attack) or CHA₂DS₂-VASc (C = congestive heart failure/left ventricular dysfunction, H = hypertension, A₂ = age [≥75 years], D = diabetes, S₂ = stroke/transient ischemic attack, V = vascular disease, A = age 65-74 years, and Sc = sex category) classification schemes; classification is based on patient characteristics, with higher scores corresponding to a higher risk for stroke.⁵⁶

The prevalence of AF rises with increasing age. In patients aged <55 years, the prevalence is approximately 0.1%, but this increases to 9.0% in persons aged \geq 80 years.¹ The cost of treating AF places a significant burden on the healthcare system.⁷ In 2005, the annual total direct cost of treating patients with AF was estimated to be \$6.65 billion.⁸ This figure, however, is dwarfed by the costs of treating stroke; in 2010, the combined direct and indirect cost of stroke in the United States was estimated to be \$73.7 billion.⁹ The mean individual life-time cost of ischemic stroke in the United States is estimated to be \$140,048.⁹

Thromboprophylaxis is the mainstay of stroke prevention in patients with AF. Based on clinical practice guidelines published by the American College of Cardiology, the American Heart Association, the American College of Chest Physicians, and the European Society of Cardiology, patients with AF should generally receive an anticoagulant (usually a vitamin K antagonist) or antiplatelet regimen (usually acetylsalicylic acid), depending on their risk for stroke and serious bleeding.^{27,10-12} Long-term therapy with a vitamin K antagonist can reduce the risk for stroke by between 62% and 68% in patients with nonvalvular AF.^{13,14}

Despite the availability of appropriate prophylaxis, thromboprophylaxis is prescribed for only approximately 50% of all eligible patients with AF.¹⁵ There is a clear need to improve the quality of care for these patients. Current quality measures for providers of treatment for AF broadly assess adherence to 3 primary areas of stroke prevention¹⁶:

- **1.** The use of pharmacologic therapy
- 2. Assessment of risk factors for thromboembolism and disease progression
- 3. Maintenance of anticoagulant therapy within recommended international normalized ratios (INRs).

Health plans may be able to improve quality of care by using available software to analyze the plan's claims data; the results may help decision makers identify practice patterns among plan clinicians and members, as well as potential opportunities to improve treatment by identifying members' stroke risk level, those not receiving appropriate, that is, guideline-based, thromboprophylaxis, and/or patients who are not being properly monitored for bleeding risk while taking an oral anticoagulant. Once identified, health plans can design patient and provider quality improvement interventions aimed at improving care for these at-risk populations.

The purpose of this study was to analyze pharmacy and medical claims data using AF-specific software to determine the risk for stroke and guideline-recommended use of anticoagulant therapy in a population of patients with a new diagnosis of AF.

Methods

Data Source

The claims data were obtained from the PharMetrics

Integrated Database from July 2008 to June 2010 (IMS Health, Inc; Danbury, CT). This deidentified database includes medical and pharmacy claims of patients enrolled by commercial insurers in the United States. The PharMetrics Integrated Database includes inpatient and outpatient claims, diagnoses, and procedures based on the *International Classification of Diseases, Ninth Revision* (ICD-9); *Current Procedural Terminology, Fourth Edition* codes; and retail and mail-order pharmacy claims in excess of 70 million individuals from more than 100 health plans.¹⁷

Study Design and Tools

This study is a descriptive, retrospective claims analysis conducted using the Anticoagulant Quality Improvement Analyzer software, a condition-specific software tool designed to evaluate population characteristics, population health risks, and appropriateness of medication use by allowing health plans to upload their pharmacy and medical claims data via a simple point-andclick method. A randomly selected 10% sample of patients from the PharMetrics Integrated Database was analyzed in this study by using this automated Health Insurance Portability and Accountability Act-compliant software tool to produce results for a series of predetermined and user-defined measures and to generate actionable, patient/prescriber-level, overall sample-specific reports. A 10% sample of this database was deemed sufficient to provide an appropriate number of patients to accurately represent treatment patterns within the population of patients with AF; indeed, nearly 26,000 patients with AF who met the inclusion criteria for this study were identified in this 10% sample.

Inclusion Criteria

Patients were included in the analysis if they met all of the following inclusion criteria:

- Their information was in the PharMetrics Integrated Database between July 2008 and June 2010
- They had a follow-up period of 12 months after AF diagnosis
- They were aged ≥ 18 years
- They had ≥1 primary or secondary diagnoses of AF
- Their pharmacy and medical claims were both recorded in the database.

Variable Descriptions

Comorbidities were identified using ICD-9 Clinical Modification diagnosis codes (Table 1).¹⁸ Measurements of stroke risk were based on the CHADS₂ and CHA₂DS₂-VASc scoring systems.

Using the CHADS $_2$ system, each patient was assigned 1 point for each of the following factors: presence of con-

Table 1	Comorbid Conditions of Interest			
Comorbidity		N (%)		
Stroke		2743 (11)		
Hypertension		16,390 (64)		
Diabetes		7015 (28)		
Heart failure		6457 (25)		
Acute myocardial infarction		795 (3)		
Coronary heart disease		8688 (34)		
Arrhythmias other than atrial fibrillation		6933 (27)		
Source: Reference 18.				

gestive heart failure (CHF), presence of hypertension (ie, systolic blood pressure [BP] >160 mm Hg), age \geq 75 years, and presence of diabetes. Two points were assigned for a history of stroke or transient ischemic attack (TIA).

The CHA₂DS₂-VASc system is another risk factorbased schema for predicting stroke and thromboembolism in patients with AF. It incorporates additional risk factors that are not included in CHADS₂. In a validation study, CHA₂DS₂-VASc was found to be superior to CHADS₂ in differentiating patients with high-risk AF from those with low-risk AF.⁶

Using the CHA₂DS₂-VASc system, each patient in the present study was assigned 1 point for each of the following factors: the presence of CHF/left ventricular dysfunction; age 65 to 74 years; presence of hypertension (systolic BP >160 mm Hg), diabetes, or vascular disease (coronary artery disease, acute myocardial infarction, peripheral artery disease, aortic plaque); and female sex. Two points were assigned for each of the following factors: age \geq 75 years and history of stroke, TIA, and thromboembolism.

Patients with AF were subsequently assigned to 1 of the following categories based on their risk factors for stroke, using both stroke risk assessment scoring systems: low risk (0 points), moderate risk (1 point), or high risk (\geq 2 points).

Outcomes

Prescribing patterns and outcomes were assessed during the 1-year period after the first occurrence of the diagnosis of AF in the study timeframe. The outcomes based on medical and pharmacy claims that were investigated included anticoagulant use, anticoagulant use by stroke risk score and age, and outpatient anticoagulant use in those hospitalized for stroke. To investigate the appropriate use of anticoagulants, levels of use and time to first gap of \geq 60 days in anticoagulant therapy were assessed. Anticoagulant use categorized by stroke risk was assessed by classifying patients into low-, moderate-, and highrisk categories as defined by CHADS₂ score. In addition, anticoagulant use by age was assessed in patients aged \geq 75 years, 65 to 74 years, and <65 years. In patients who were hospitalized for stroke, the rate of anticoagulant use in the outpatient setting was also investigated.

Results

Patient Demographics

A total of 25,710 patients with AF were analyzed; 58% of the patients were male. The mean age of patients

Table 2	Patient Characteristics		
Demographic characteristics		Patients	
All patients, N		25,710	
Sex, N (%)			
Female		10,781 (42)	
Male		14,929 (58)	
Average age, yr		71.6	
Female		74.26	
Male		69.68	
Risk score, N (%)			
CHADS ₂			
Low (0)		4442 (17)	
Moderate (1 point)		7313 (28)	
High (≥2 points)		13,955 (54)	
CHA ₂ DS ₂ -VASc			
Low (0)		1672 (7)	
Moderate (1 point)		3178 (12)	
High (≥2 points)		20,860 (81)	

was 71.6 years (74.3 for female patients and 69.7 for male patients). Using the CHADS₂ system, the proportions of patients at low, moderate, and high risk for stroke were estimated to be 17%, 28%, and 54%, respectively. Using the CHA₂DS₂-VASc system, the proportions of patients at low, moderate, and high risk for stroke were estimated to be 7%, 12%, and 81%, respectively (**Table 2**).

Anticoagulant Use

Among the total AF population in this study, based on claims data, 9093 (35%) patients with AF received anticoagulant treatment to reduce the risk for stroke and 16,617 (65%) did not (**Table 3**). Because the data used in this analysis were collected only up to June 2010, newer oral anticoagulant agents were not included. Of the 9093 patients who received an anticoagulant, 4877 (54%) had a gap of \geq 60 days in therapy. The mean time from initiation of anticoagulation to interruption of therapy was 166 days.

Anticoagulant Use, by Stroke Risk and Age

Based on the CHADS₂ scoring system, the rates of anticoagulant use in patients with AF were found to be relatively low, even in patients deemed to be at a high risk for stroke. Overall, based on claims data, only 39% of patients in the high-risk category received an anticoagulant. However, rates varied by age-group, with 16%, 22%, and 61% of patients aged <65 years, 65 to 74 years, and \geq 75 years, respectively, receiving an anticoagulant. In the moderate-risk category, 39%, 40%, and 21% of patients by age stratification of <65 years, 65 to 74 years, and \geq 75 years, respectively, received an anticoagulant; and in the low-risk category, 60%, 40%, and 0% of patients, respectively, received an anticoagulant (Table 3).

Rate of Outpatient Anticoagulant Use in Patients Hospitalized for Stroke

Based on claims data, the rate of preadmission out-

Table 3 Anticoagulant Use, by Stroke Risk and Age						
Patients receiving	Age-group, yr					
anticoagulant, by CHADS ₂ risk group ^a	<65 (N = 7952) N (%)	65-74 (N = 6736) N (%)	≥75 (N = 11,022) N (%)	All age-groups (N = 25,710) N (%) ^a		
High risk	879 (16)	1216 (22)	3319 (61)	5414/13,955 (39)		
Moderate risk	954 (39)	992 (40)	529 (21)	2475/7313 (34)		
Low risk	725 (60)	479 (40)	0 (0)	1204/4442 (27)		
All risk groups	2558 (32)	2687 (40)	3848 (35)	9093/25,710 (35)		
^a Percentages represent proportion of patients receiving anticoagulant therapy in that risk group.						

patient anticoagulation was low in patients who were hospitalized for stroke. Of the 616 patients who were hospitalized for stroke, 173 were treated with an anticoagulant in the outpatient setting, representing 28% of the total (**Table 4**).

Discussion

Current medical guidelines for stroke prevention recommend that all patients with AF who are at high risk for stroke receive thromboprophylaxis, unless contraindicated.^{2,7,11,12} Appropriate thromboprophylaxis has been shown to reduce the risk for ischemic stroke by approximately 60%.^{13,14} However, studies have shown that nearly 50% of patients with AF do not receive appropriate thromboprophylaxis.^{15,19,20}

In our analysis, 65% of patients with AF captured in the PharMetrics Integrated Database did not have claims for anticoagulation therapy. Even among patients at high risk for stroke, 61% did not have a claim for an anticoagulant. Furthermore, among patients with AF who were subsequently hospitalized for stroke, 72% did not have a claim for an anticoagulant medication in the outpatient setting before hospitalization. Our findings, based on data before the availability of the newer anticoagulant agents, are consistent with the past literature, providing further evidence of the need to improve the management of AF in the outpatient setting.

The ramifications of stroke can be devastating for patients and costly for health plans. Stroke is the third most common cause of death in the United States and a leading cause of long-term morbidity.³ The mean lifetime cost of ischemic stroke in the United States is estimated to be \$140,048.⁹ AF is one of the 20 medical conditions identified by the Centers for Medicare & Medicaid Services and the National Quality Forum that impose heavy health burdens on patients and collectively account for more than 95% of Medicare's costs.²¹ These figures highlight the need for improved management of AF to reduce the incidence of stroke.

Several reasons explain why physicians and patients may find it challenging to manage the risk of AF-related stroke effectively. Physicians may struggle with the complexities of stratifying stroke risk in patients with AF. More than a dozen stroke risk–stratification systems for patients with AF have been proposed, based on various combinations of clinical and echocardiographic predictors, and although CHADS₂ and CHA₂DS₂-VASc are the most frequently used systems, none has been convincingly shown to be "the best."²²

Physicians also may have concerns about cognitive and physical impairment having an impact on the decision-making process for elderly patients and may be reluctant to prescribe anticoagulants for this population.²³

Table 4	Outpatient Anticoagulant Use in 25,710 Patients Hospitalized for Stroke			
Variable		Patients, N (%)		
Inpatient stroke hospitalization		616 (2)		
Untreated with anticoagulant in outpatient setting		443 (72)		
Treated with anticoagulant in outpatient setting		173 (28)		

Risk stratification necessitates an estimate not only of stroke risk but also of risk for bleeding. The risk for bleeding, risk for falls, and patients' ability to comply with treatment also have been identified as important physician concerns that may lead to a clinical decision to limit anticoagulation therapy in the elderly.²⁴ As the clinician considers bleeding risk, he/she must also differentiate between the likelihood of a minor bleeding event versus a major bleeding episode.

Lane and Lip note that "physicians may not adhere to the guidelines because they are either not aware of them or their knowledge of them is poor."²⁵ They also suggest that failure to adhere to clinical practice guidelines "may be because the guidelines are deficient in terms of evidence-based information," and physicians may feel that this limits the applicability of these guidelines to certain patients.²⁵

Patients, as well as healthcare providers, may fail to adhere to published guidelines for anticoagulation therapy in AF. For example, we found that 54% of patients in our study had a gap in therapy of >60 days. Such treatment gaps may have numerous causes. Often, patients have a limited understanding of the value of vitamin K antagonist therapy for stroke prophylaxis, and many are unaware of the risks associated with overanticoagulation or underanticoagulation. As a result, INR monitoring visits at anticoagulation clinics are frequently missed, INR values are frequently out of range, and dose adjustments are often required, particularly in the elderly.²⁶ In addition, treatment with a vitamin K antagonist is also often perceived as a burden on lifestyle, restricting diet, social life, career, independence, and physical activities.²⁶

Despite the increasing prevalence of AF and related complications, there has been limited focus on quality improvement activities in outpatients. The Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse identifies 45 heart failure–specific quality measures and 71 diabetes-specific measures, but only 6 AF-related measures, all of which address stroke prevention.²⁷

The American Recovery and Reinvestment Act of

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2009 called on the Institute of Medicine to recommend a list of priority topics in comparative effectiveness research (research designed to inform healthcare decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options) that deserve federal support. AF is within the top quartile of priorities.²⁸ The software tool used in this study offers an effective and easy-to-use method for retrospectively analyzing claims data, helping to identify patients with AF who are at high risk of stroke, and highlighting whether healthcare providers are managing that risk appropriately based on guideline recommendations.

Health plans; Pharmacy & Therapeutics committees; and medical, pharmacy, and quality improvement directors may find it beneficial to use the findings generated by this software to implement targeted educational programs for patients and healthcare providers regarding the importance of stroke prevention among patients with AF and recommended guidelines to determine the need for anticoagulant prophylaxis.

Limitations

There are a number of limitations to this study. First, we cannot guarantee the completeness and accuracy of the medical claims data used in this analysis. Claimsbased analyses rely on data that are used primarily for administrative (ie, billing, payment, and operations) purposes. The data do not, therefore, necessarily reflect all of the clinical variables taken into account by physicians when making treatment decisions; therefore, some clinical characteristics (eg, INR, contraindications to anticoagulant therapy) will not have been captured, and there is the potential for some patients to have been misclassified in claims data that are included in the PharMetrics Integrated Database.

An assessment of bleeding risk should be part of a patient assessment before starting anticoagulation therapy. Our analysis did not include bleeding risk, resulting in a potential overestimate for undertreatment. Furthermore, the data captured in this analysis cover only a short period of patients' medical histories; the information was limited to prescribing patterns and outcomes during the 1 year after the diagnosis of AF. The data may have omitted relevant risk-related events that occurred before the diagnosis of AF (eg, a previous stroke), and this might have led to underestimations of stroke risk scores.

Another area that is not captured by the medical claims database is over-the-counter medication use. Therefore, there are no data regarding the use of aspirin.

Finally, this analysis considered only patients for whom both medical and pharmacy claims data were available. Patients who had only medical or only pharmacy data included in the database were discounted, and this might have affected the overall results.

Conclusions

Given the enormous clinical and economic impact of AF-related stroke, AF is an ideal target for quality improvement efforts. Based on medical and pharmacy claims data obtained from the PharMetrics Integrated Database, our analysis showed that 54% of patients diagnosed with AF were at a high risk of stroke according to CHADS₂ criteria. Of these patients, 61% did not have a claim for anticoagulant therapy. Furthermore, among patients who were hospitalized for a new stroke, more than 70% did not have a claim for an anticoagulant agent in the outpatient setting. This claims-based analysis supports the findings seen in the past literature that many patients with AF are not receiving appropriate thromboprophylaxis to counter their risk for stroke.^{15,20}

Anticoagulant use for the prevention of stroke in patients with AF appears suboptimal. Increased use of appropriate anticoagulation therapy has the potential to reduce the incidence of stroke, along with associated fatalities and morbidities. ■

Author Disclosure Statement

Dr Patel, Dr Macomson, Dr Nelson, Dr Mody, and Dr Schein are employees of Janssen and shareholders of Johnson & Johnson; Ms Lennert is an employee of Xcenda; and Dr Owens is a consultant to Allergan, Auxilium, Biogen Idec, Boston Scientific, CardioDx, Eli Lilly, Eyetech, Genzyme, Janssen/Johnson & Johnson, and Q Pharma.

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STAKEHOLDER PERSPECTIVE

The Enormous Impact of Atrial Fibrillation and Stroke on Patients, Payers, and Society

The enormity of the impact of atrial fibrillation (AF) and subsequent strokes cannot be overstated. The outcomes of strokes for patients, caregivers, and payers (regardless of payment classification) are devastating. As the US population of those aged >65 years surges, now and certainly in the long-term, acute AF and the potential for stroke have enormous consequences for the individual patient and for society.

SOCIETY: According to the Centers for Medicare & Medicaid Services, approximately 8.6% of Medicare recipients aged >65 years have suffered a stroke.¹ The death rate for those who have had a stroke is 40.7 per 100,000 persons.¹ The sheer listing of death rates does not encompass the socioeconomic, family, payer, or societal factors that are affected by cerebrovascular disease, such as the occurrence of a stroke. Therefore, it is crucial for comprehensive examinations of sophisticated computer modeling of varying components that are enhancing outcomes research to

become more commonplace than presently is the case in the United States.

Since 1999, the National Institute for Health and Clinical Effectiveness (NICE) has served as a reference and guidance bureau for assessing, guiding, and monitoring outcomes-based research pertaining to the public health in the United Kingdom.² The NICE framework encompasses the sophistication necessary to evaluate all components of the UK National Health Service providing universal coverage for British citizens. Many stakeholders believe that a similar framework for outcomes research could provide dividends for many aspects of health conditions (ie, AF and stroke) in the United States as well.

PATIENTS/CAREGIVERS: Many newer treatment options for AF and stroke prevention have recently become available. Novel oral anticoagulants have been shown to be equally as effective as warfarin, the standard treatment for decades, and the

STAKEHOLDER PERSPECTIVE (continued)

newer agents do not require monitoring,³ thereby increasing the prescribing options for stroke prevention in patients with AF, as well as decreasing the long-term costs that are associated with the treatment of patients with AF.

As noted, the long-term healthcare costs of stroke and its sequelae are substantial. With the expected increase in the Medicare population over the coming decades, there is an urgent need for an enhanced emphasis on the necessity for effective preventive care afforded by appropriate treatments for AF to avoid the long-term costs and impacts on patients, caregivers, and families.⁴

PAYERS/PROVIDERS: From a quality-improvement perspective, as well as from an enhanced opportunity for advanced assessment of health outcomes, the techniques, research design, and the important data derived from the present study by Dr Patel and colleagues provide a model template for many researchers, stakeholders, and payers. All those who are involved in this condition can see the path to providing betterinformed treatment options for patients with AF as a crucial benefit from studies such as the one presented in this article. The avoidance of the enormous impact of stroke as a consequence of untreated or undertreated AF is an important consideration for so many who have a stake in this condition.

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