Research to Real-World Application: Experts Weigh In on the Underuse of Anticoagulants

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This article is the first in a 2-part series that summarizes the proceedings from a roundtable meeting that was conducted to discuss real-world considerations in nonvalvular atrial fibrillation and venous thromboembolism.

Abstract

Although numerous studies have shown that anticoagulants can reduce the risk of stroke and thromboembolic events in patients with nonvalvular atrial fibrillation, they are underprescribed in the clinical setting. While standardized risk scoring assessments are recommended in treatment guidelines to determine when anticoagulant use may be appropriate, they are not widely used in the real-world clinical setting. Many factors contribute to anticoagulant underuse, including patient characteristics and comorbidities. Reluctance to prescribe an anticoagulant may also stem from concerns about bleeding or other perceived risks. In addition, physicians may be discouraged from prescribing anticoagulant therapy, particularly warfarin, if follow-up care and monitoring is potentially unfeasible. Patient fears of treatment and lack of access to the healthcare system also contribute to underuse. Increased awareness and education, medical therapy management programs, better care coordination, and improvements in monitoring and follow-up programs may help to increase the use of anticoagulant therapies in appropriate patients.

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For author information and disclosures, see end of text.

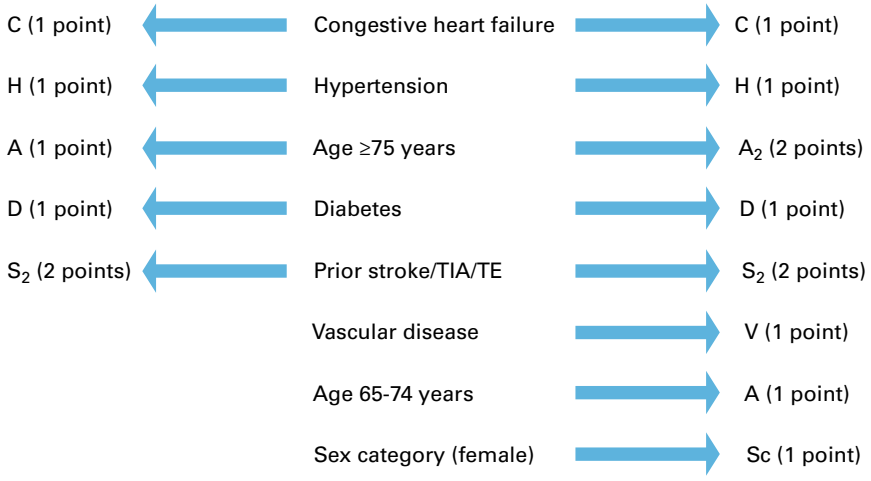
Clinical trials are designed to show safety and efficacy in a controlled setting. However, prescribers and payers have to look beyond clinical trial data to make decisions in a real-world setting. Real-world considerations vary by disease state and therapeutic area. The content for this supplement was based on applicable discussion points and data presented at a roundtable discussion entitled *Research to Real-World Application: Considerations for Use of Health Economic and Outcomes Data in Anticoagulation*.

The multidisciplinary panel included clinical experts, medical and pharmacy directors from health plans, epidemiologists, and health economists. One of the topics discussed during the roundtable was the underuse of anticoagulants. Participants discussed factors associated with the underprescribing of anticoagulants among patients with nonvalvular atrial fibrillation (NVAF) and the effect of underuse on outcomes. Compared with venous thromboembolism (VTE), which typically requires anticoagulation therapy for a defined period of time, NVAF is a chronic condition, and patients tend to be older and need long-term anticoagulant prophylaxis.[1,2] These factors are important to consider when discussing the underuse of anticoagulants for patients with NVAF.

Anticoagulation Underuse

Oral anticoagulant therapy with vitamin K antagonists (eg, warfarin) are known to reduce the risk of stroke in patients with NVAF. A 2007 meta-analysis by Hart et al reported results of published randomized controlled trials and found that warfarin was associated with a relative risk reduction of 64% for stroke.[3]Despite clear benefits associated with the use of anticoagulants, estimates suggest that approximately

Figure 1. $CHADS_2$ and CHA_2DS_2-VASc Risk Scoring Systems[7,a]



TE indicates thromboembolism; TIA, transient ischemic attack.
[a] American College of Cardiology/American Heart Association/Heart Rhythm Society 2014 Anticoagulation Recommendations: CHA_2DS_2–VASc 1, no antithrombotic therapy, aspirin, or oral anticoagulant may be considered; CHA_2DS_2–VASc ≥2, oral anticoagulant is recommended.

one-half to two-thirds of the patients for whom anticoagulation therapy is recommended actually receive it.[2,4,5] A recent claims analysis in patients with NVAF found that there is also an economic impact related to underuse. Stroke-related medical costs were 60% lower (P <.001) for individuals who received and were adherent to warfarin therapy than for those who did not receive warfarin.[6]

The reason why this quality gap exists is multifactorial. Although the decision to prescribe an anticoagulant is largely based on a physician's assessment of benefit (reducing the risk for stroke) versus risk (potential for increased bleeding),[7] there are many other real-world factors to consider. These include a patient's comorbidities, concomitant medications, and likelihood of receiving follow-up care, as warfarin requires frequent monitoring to ensure that patients are in the optimal therapeutic range. Newer treatments, including the factor Xa inhibitors rivaroxaban and apixaban and the direct thrombin inhibitor dabigatran, offer important advances over warfarin in terms of onset of action, predictability of pharmacological profiles, and a lower risk of drug-drug interactions, and thus may offer fewer barriers to use.[7] However, long-term clinical data are needed to determine whether any advantages associated with these oral therapies will translate to increased use. Several studies exist with older agents that can help shed light on the extent to which anticoagulants are underused, and some of the barriers to prescribing.

Individual characteristics are predictors of whether a patient receives anticoagulation therapy. In a retrospective observational study of 44,193 patients with atrial fibrillation (AF), Agarwal and colleagues investigated patient-related demographic and clinical factors that influence warfarin and other anticoagulant use.[5] The investigators used hospitalization claims data from approximately 250 general medical and surgical hospitals across the United States to characterize patient diagnoses, treatments, and procedures, and to calculate stroke risk scores ($CHADS_2$ scores; **Figure 1**).[5,7] Agarwal and colleagues observed that 56% of patients with AF received anticoagulation with warfarin. Several factors were associated with decreased likelihood of receiving warfarin, with or without INR monitoring (**Table 1**).[5] These included bleeding risk factors such as hepatic disease (P <.0001), renal disease (P <.0001), aspirin use (P = .0153), and the presence of fractures (P <.0001). In addition, gender had an effect; women were less likely to receive warfarin than men (P = .0004). Age was also an important factor in warfarin use. Patients 75 years and older were less likely to be treated with warfarin compared with those aged 40 to 59. Likewise, several factors increased the likelihood of receiving anticoagulants. Patients with $CHADS_2$ scores of 2 or 3 were more likely to receive warfarin than patients with a $CHADS_2$ score of 0 or 1. Patients with congestive heart failure were also more likely to receive an anticoagulant (P <.0001). Data also showed that patients admitted to the hospital through routine admission were more likely to be prescribed warfarin than patients admitted through an emergency department (P <.0001). The findings show that patterns of warfarin use reflected physicians' percep-

Table 1. Predictors of Warfarin Use[5]

Reduced likelihood of receiving warfarin	Increased likelihood of receiving warfarin
Being female	Being between 60 and 74 years old
Being at least 75 years old	Congestive heart failure or vascular malformation
Hepatic disease	$CHADS_2$ risk score of 2 or 3
Aspirin use	Routine hospital admission[a]
Presence of fractures	
Renal disease	

[a]Versus emergency department admission.

tions of risk for stroke and bleeding in patients, especially in patients at least 75 years old.[5]

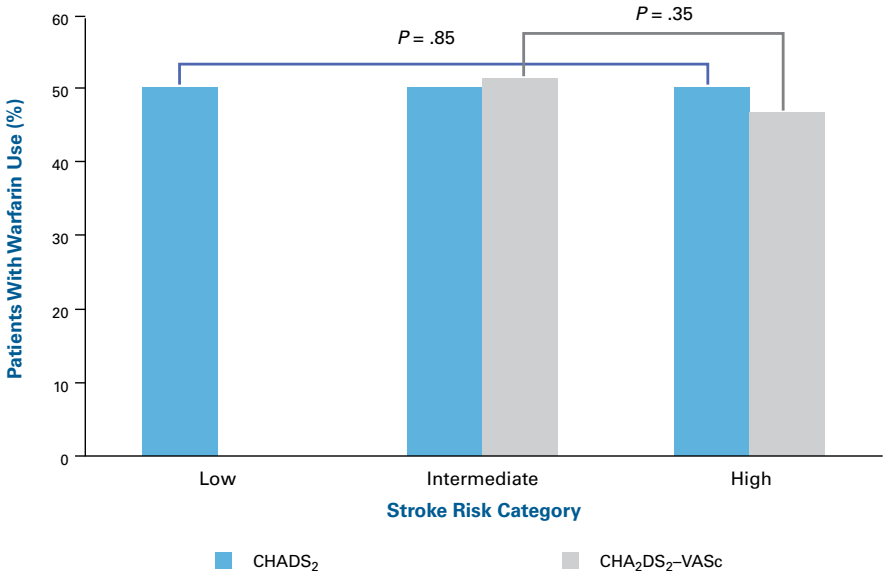
The faculty participants commented that the efficacy of warfarin in reducing the risk for stroke in patients with NVAF has been well established. The participants also agreed that anticoagulants were underused and that it has been an issue for many years. "I do not think there is anybody in managed care that is going to argue that warfarin is underused or anticoagulants are underused," noted Jeffrey Dunn, PharmD, MBA. Joseph Biskupiak, PhD, MBA, agreed, stating that his organization has observed underuse across multiple data sources. "We have looked at this issue in an electronic medical record [EMR]. We have looked at this in a claim's database. We have looked at this in our institution," Dr Biskupiak stated. "I can tell you across the board nationally, locally, wherever you look, we see underutilization." Panelists then discussed the difficulties in determining why anticoagulants were underused and commented that patients' preferences and attitudes toward their use should not be overlooked. The consensus among participants was that there is no way to know for sure why some patients are not prescribed an anticoagulant. Claims data and EMRs do not capture physicians' reasons for not prescribing; they do, however, show prescribing trends.

Assessing the Risk of Stroke

Treatment guidelines recommend the use of the $CHADS_2$ or CHA_2DS_2-VASc scoring system to assess the risk of stroke in patients with NVAF and whether to initiate anticoagulation therapy (**Figure 1**).[7-9] However, roundtable participants noted that while stroke risk scoring systems are useful to determine whether an anticoagulant should be prescribed, risk scores are seldom calculated in real-world clinical settings. Specialists are more likely to calculate risk scores, but primary care physicians (PCPs) are often unfamiliar with or lack the time to determine a patient's risk score. According to the faculty participants, risk scores are used mostly in clinical research and by payer pharmacy and therapeutics (P&T) committees to compare treatment effects. Payers do not require physicians to provide a risk score for reimbursement. Dr Biskupiak commented, "I do not know anybody [that] uses these risk scores except people like me who do research because prescribing does not vary by risk score." Panel members noted that most PCPs refer their patients to a cardiologist for a diagnosis rather than taking up time during an office visit to calculate the $CHADS_2$ score and come to an informed decision about anticoagulation. One panelist commented that $CHADS_2$ scores are sometimes used to predict the risk of stopping anticoagulant therapy or whether a patient should be bridged off warfarin to have surgery, even though the risk scores were not created for this purpose.

Despite guideline recommendations that anticoagulant use should be based on standardized risk scores (eg, CHA_2DS_2-VASc; **Figure 1**),[7] some data suggest that use does not vary across the risk strata. In 2011, Sandhu and colleagues examined data from administrative databases (2000-2005) recording clinical characteristics and inpatient and outpatient pharmacy claims data for newly diagnosed patients with NVAF, 65 years and older in Alberta, Canada (n = 8780), to examine the relationship between warfarin use or nonuse and outcomes. Patients were stratified using $CHADS_2$ and CHA_2DS_2-VASc score as low (0), intermediate (1), and high risk (≥2). In a sensitivity analysis excluding patients with contraindications to warfarin use, warfarin use was 51.0% among low-risk, 50.5% among intermediate-risk, and 52.3% among high-risk patients based on $CHADS_2$ risk scores. Based on CHA_2DS_2-VASc risk scores, use was 51.6% among intermediate-risk patients and 54.1% among high-risk patients (**Figure 2**).[4] That is, a large proportion of patients with a high risk of stroke were not prescribed warfarin and an approximately equal proportion of those in the low-risk category for stroke were prescribed warfarin.[4]

Figure 2. Rates of Warfarin Use by $CHADS_2$ and CHA_2DS_2-VASc Risk Categories[4]



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In a recent retrospective analysis of claims data from 105,397 patients with AF from 5 US databases (3 commercial, 1 Medicare, and 1 Medicaid), Lang and colleagues evaluated patterns of anticoagulant underuse for AF. The researchers calculated $CHADS_2$ and CHA_2DS_2-VASc scores for all patients and assigned each to low risk (0 points), moderate risk (1 point), or high risk (≥ 2 points). Claims data were used to determine warfarin use. Lang et al found that use of anticoagulants ranged from 16% to 39% across all databases. Warfarin use in high-risk patients was slightly higher, ranging from 19% to 51% (**Figure 3**).[10] In this high-risk population, warfarin use was lowest among Medicaid patients (19%).[10]

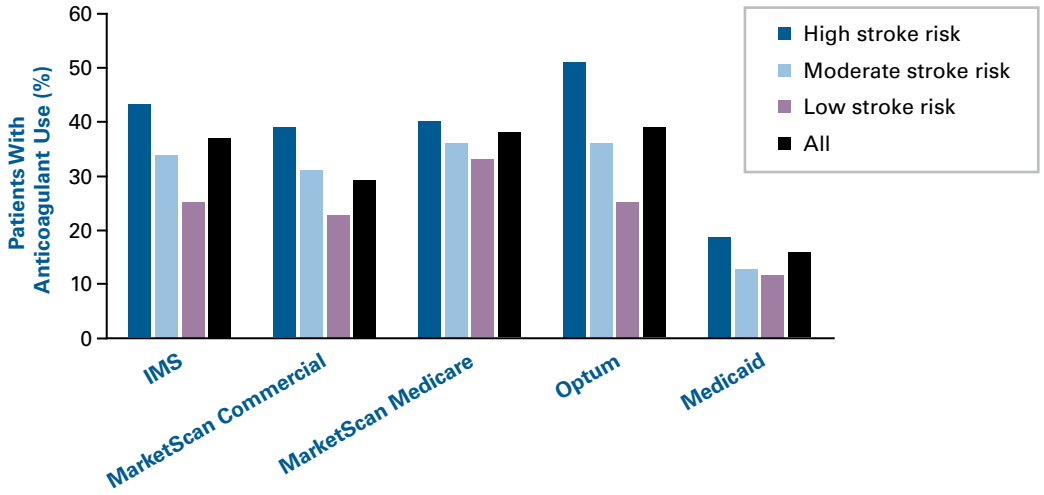
Participants noted that it is difficult for managed care to track underuse by risk score. Currently, $CHADS_2$ and CHA_2DS_2-VASc risk scores are not tracked through the use of EMRs, and the scores are not captured on claims data. One participant stated that his institution does not use risk scores in its utilization management programs. Some faculty noted that not having these risk scores made managing NVAF more difficult. Dr Biskupiak added, "We know underuse is a problem, but we cannot get at the score. We do not know by score who is getting it or not getting it."

In their discussion, the faculty noted that there is a difference between inpatient and outpatient settings. Edmund Pezalla, MD, MPH, stated, "In the inpatient setting, a lot of this is done, but in the outpatient world, none of this is happening. We need to realize that there is a dichotomy between the inpatient and outpatient worlds." Fadia T. Shaya, PhD, MPH, added that gaps in therapy also largely occur during care transitions, from inpatient to outpatient settings. Many PCPs are unaware of risk scores, noted another participant. In his market, the vast majority of PCPs are in solo practice and tend to be isolated from specialty recommendations of risk assessment.

Reasons for Underprescribing

In the real-world setting, the decision regarding whether to prescribe anticoagulants is centered on weighing the short-term risk for stroke against the concern for increased bleed risk,[7] but according to the participants, this is usually done without the use of standardized risk scores. The participants agreed that most physicians prescribe anticoagulants for secondary stroke prevention. Tomás Villanueva, DO, MBA, FACPE, SFHM, stated, "Most likely with someone who has had a stroke, it is just automatic that we are heading that route." For primary stroke prevention, healthcare providers are sometimes reluctant to prescribe an anticoagulant. The majority of participants cited a fear of causing a bleed as the most common reason for not prescribing an anticoagulant. Evidence suggests that fears of bleeding may outweigh concerns for stroke risk when deciding whether to initi-

Figure 3. Anticoagulant Use Among AF Patients, by Risk Category[10]



AF indicates atrial fibrillation; IMS, information management system.
Reprinted with permission from Lang K, Bozkaya D, Patel AA, et al. *BMC Health Services Research.* 2014;14:320-338.

ate warfarin therapy.[10] This occurs despite evidence that indicates major bleed events are rare (≤1%).[11] A retrospective cohort study of 945 inpatients with AF found that while high-risk stratification did not predict warfarin use, history of stroke/transient ischemic attack/embolic event and actual and perceived bleeding risk were predictive.[11]

Faculty participants suggested that in addition to bleed risk, the burden of INR monitoring factors into the underprescribing of anticoagulants. Several faculty noted that healthcare practitioners could be reluctant to prescribe warfarin if they suspect that INR monitoring and follow-up care is either unfeasible or unlikely. Factors contributing to underprescribing include a patient's fear of treatment, lack of access to the healthcare system, the inability of the patient to be monitored regularly, and lack of relationship with a provider. Factors related to cost, deductibles, and remuneration were also identified as barriers to use. Some of the faculty participants referred to the Lang et al study finding that Medicaid patients were less likely to be prescribed warfarin than Medicare patients or patients with commercial insurance plans.[10] This finding was consistent with their experiences. Several participants acknowledged that there is a discrepancy in care based on socioeconomics, and that patients with a lower socioeconomic status are less likely to have follow-up care. Physicians do not want to prescribe warfarin if they believe a patient will not be monitored, because treatment in patients whose INR falls outside the therapeutic range increases the risk for adverse events. Geno J. Merli, MD, FACP, FHM, FSVM, stated, "Nobody wants to put them on [warfarin] and wonder where they get the rest of their care." Dennis B. Liotta, MD, MBA, shared information regarding a study his organization conducted in AF patients. The results seemed to indicate warfarin use was associated with increased risk for strokes; however, a closer look at the data revealed that INR monitoring played a key role in outcomes. "Patients on warfarin that were not being monitored for INR were the ones that were having all the strokes," stated Dr Liotta. "Monitoring is important, and I am afraid that monitoring does not get done enough."

Other Contributing Factors

Participants discussed other factors involved in the underuse of anticoagulants in a real-world setting, noting that clinical studies typically do not include very complex patients. Several faculty noted that physicians may be reluctant to prescribe an anticoagulant in certain situations. Providing 1 example, Donald C. Balfour III, MD, FACP, explained, "I am thinking cognitive status. Do they have a caregiver that is going to give them medication every day? There are so many issues, but I think it is fear on the physician's part." Participants also proposed that patient comorbidities and polypharmacy were important factors. Dr Shaya noted that patients in the real world are typically more complex, older, and have more illnesses than those enrolled in clinical trials; they

often face major issues with managing their medications and adhering to treatment regimens.

Finally, faculty discussed the lack of incentives to reduce readmissions of NVAF patients, even in institutions that focus on transitions in care. Resources are focused on larger readmission issues such as heart failure, pneumonia, chronic obstructive pulmonary disease, and total hip and knee replacement, according to the faculty. Anticoagulation is a small piece. Dr Balfour stated, "We have over 100 quality measures that our primary care physicians have to follow, and this is not one of them."

In 2010, an estimated 5.2 million people in the United States had AF, and that number is projected to increase to 12.1 million by 2030.[12] Still, in a noisy healthcare world, priority for transitions in care is given to the disease states that are incentivized, according to the participants. Quality measures, such as Healthcare Effectiveness Data and Information Set, are on the minds of payers and providers. One participant noted that most of the time, hospital systems focus their efforts on what is reportable to CMS, which tracks all-cause readmissions, and this impacts reimbursement.[13] However, several faculty participants commented that, compared with other conditions, AF is not seen as a major cause of readmission. Furthermore, healthcare providers do not have the time or resources to also evaluate $CHADS_2$ scores and anticoagulant underuse. The general consensus from panel members is that many conditions require increased focus, but there are limited resources available. At this point in time, AF is not one of CMS's key priorities. "How big an issue is it in the grand scheme of things? This is why it has not been incented—because there are so many other gigantic priorities that we have not got a handle on," Dr Merli said.

Future Improvements

Participants discussed ways to address the problem of underuse. One way to address gaps in care is through increased awareness and education; another is through medical therapy management (MTM) programs and better care coordination. Dr Dunn noted that with the greater emphasis on MTM and integrated care management, the use of anticoagulants may increase. He stated, "There are a lot more of these MTM companies springing up, so I think in the next couple of years, you are going to see cardiovascular disease, AF, and some of these others expanded to have more of a pharmacist interventional approach to managing the drugs."

The faculty also discussed strategies for improving monitoring. One participant noted that his medical group has taken an organized approach to INR monitoring and created an anticoagulation clinic in its cardiology department that is supervised by cardiologists and run by nurses. The medical group observed that after this program was initiated, the percentage of AF patients within therapeutic range was very high. Panelists also discussed partnerships with retail clinics to provide a community-based monitoring system. Dr Shaya noted that the trend toward community-based care and more patient engagement could improve the management of AF patients. "We are going into the community for many other conditions—hypertension treatment and monitoring, blood pressure, and diabetes," she added. Addressing gaps in care with anticoagulation could be done in the same way.

Dr Dunn reiterated that incentives play a key role in increasing the focus on a particular disease state or issue. Adding quality measures pertaining to anticoagulant use or readmissions related to AF would impact care. "Next week, if CMS was going to start looking at atrial fibrillation management, you would have a whole focus on the process," Dr Dunn said.

Conclusions

Despite their acknowledged efficacy, anticoagulants are underprescribed in patients at high risk for stroke and thromboembolic events.[4,5] Risk stratification methods, such as $CHADS_2$ and CHA_2DS_2-VASc, are not widely used. While these scoring systems are understood and used by clinical researchers, specialists, and payer P&T committees, typically they are not used by general practitioners. In many healthcare systems, risk scores are not recorded in utilization management programs. In real-world practice, practitioners may decide against prescribing anticoagulants due to real or perceived immediate risks, such as the risk of bleeding or other conditions the patient may have.

The burden of monitoring patients receiving warfarin is another factor. Although warfarin is the standard of care and is relatively inexpensive, physicians may be reluctant to prescribe it to a patient for whom monitoring is unlikely or infeasible. A patient's lack of access to the healthcare system, lack of a relationship with a provider, or inability to regularly take medications are also factors regularly considered when prescribing. Providers have further considerations for patient safety related to polypharmacy.

Thus, although anticoagulants are efficacious, practitioner and payer concerns are real-world factors in the decision-making process that lead to the underuse of anticoagulants. Improvements in monitoring, MTM programs, increased patient engagement, and the use of quality measures or other incentives are all strategies that could lead to increased use of anticoagulation therapy in appropriate patients.

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