UNDERUSE OF ORAL ANTICOAGULATION THERAPY IN OLDER ADULTS WITH ATRIAL FIBRILLATION AFTER STROKE

Cecily Robin Smith

A project submitted to the faculty at the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctorate of Nursing Practice in the School of Nursing.

Chapel Hill
2018

Approved by:

Carrie Palmer

Hugh Waters

Robin Lang

© 2018
Cecily Robin Smith
ALL RIGHTS RESERVED

ABSTRACT

Cecily Robin Smith: Underuse of Oral Anticoagulation Therapy in Older Adults with Atrial Fibrillation After Stroke
(Under the direction of Carrie Palmer)

Background and Purpose: There was an identified underuse of oral anticoagulation (OAC) among individuals who were over the age of 65 with atrial fibrillation (AF). The purpose of this DNP project was to identify patients aged 65 or older with a diagnosis of AF and a cerebral vascular accident (CVA) or transient ischemic attack (TIA), not on current OAC to determine if a prescription was provided to them at time of discharge from the hospital or during a post-hospitalization follow up appointment with their primary care or cardiology provider.

Method: A retrospective medical record review was used over a three-month period in 2016 to determine clinical practice of providers prescribing OAC to patient ages 65 and older with AF and known stroke or TIA diagnosis. An evidence-based clinical decision support algorithm for the treatment of those with AF who had a CVA or TIA was implemented over a 12-week period at a large, independent hospital using the ACE Star Model of Knowledge Transformation, a framework for putting evidence-based processes into operation. The risk for stroke and bleeding was calculated using the CHA_2DS_2-VASc score and HAS-BLED tools. Following the implementation period, the same three-month span was selected in 2017 for a retrospective record review to determine the effectiveness of the intervention.

Results: A total of 27 patients were included in this project. The number of eligible patients who were offered prescriptions for OAC increased from 87% in 2016 to 100% in 2017.

Conclusion: The intervention resulted in the desired change towards evidence-based practice among providers. Following implementation of the project discharging providers not only included neurology's recommendations in their discharge notes, but also provided prescriptions to eligible patients rather than leaving it to the patient's primary care provider to initiate.

TABLE OF CONTENTS

LIST OF TABLES

Table

LIST OF ABBREVIATIONS

ACC	American College of Cardiology
AHA	American Heart Association
AF	Atrial Fibrillation
CVA	Cerebral Vascular Accident
$CHADS_2$	Congestive Heart Failure, Hypertension, Age ≥ 75 Diabetes Mellitus, Stroke or Transient Ischemic Attack
CHA_2DS_2-VASc	Congestive heart failure, Hypertension, Diabetes mellitus, history of Stroke /Transient Ischemic Attack, Thromboembolism, Vascular disease, Age, and Sex
DOACs	Direct Oral Anticoagulants
EMR	Electronic Medical Record
FFP	Fresh Frozen Plasma
HRS	Heart Rhythm Society
HAS-BLED	Hypertension, Abnormal liver/renal function, Stroke history, Bleeding predisposition, Labile international normalized ratio, Elderly, and Drug/alcohol usage
ICH	Intracranial Hemorrhage
INR	International Normalized Ratio
PCP	Primary Care Providers
OAC	Oral Anticoagulation
SD	Standard Deviation
TIA	Transient Ischemic Attack
VKA	Vitamin K Antagonist

CHAPTER1: Introduction

Atrial fibrillation (AF) is the most common cardiac arrhythmia affecting 5% of individuals over the age of 65. Atrial fibrillation carries a five-fold higher risk for an ischemic stroke compared to adults without the diagnosis. As individuals with AF age, their risk for a stroke increases, making AF the single most probable cause of ischemic strokes among older adults (Sellers & Newby, 2011). The number of individuals with AF is expected to increase due to the aging baby boomer population thus increasing the number of individuals at risk for having a stroke, specifically an embolic stroke (Khan, Huang & Datta, 2016). The mortality rate associated with AF-related strokes is higher than those not related to AF, and there is greater disability, longer hospitalizations, and poorer functional outcomes in AF-related strokes (Lip, 2013; Padjen, Jovanovic, Leys, & Beslac-Bumbasirevic, 2013). The increased risk for stroke is similar with either paroxysmal AF or sustained AF (Meschia et al., 2014).

Stroke in the setting of AF creates a high suspicion for cardioembolic etiology. Age is also an associated risk for an embolic stroke. Oral anticoagulation therapy (OAC) has been found to be highly effective in preventing thromboembolism, thus reducing stroke risk in individuals with AF and extending the lives of many (Kirchhof et al., 2016). According to the American College of Cardiology/American Heart Association/Heart Rhythm Society (ACC/AHA/HRS) guideline (January et al., 2014), the CHA2DS2-VASc score is recommended to determine stroke risk in patients with nonvalvular atrial fibrillation (NVAF) (Table 1). A CHA_2DS_2-VASc score of > 2 is considered a high stroke risk score and initiating OAC is recommended (Odum, Cochran, Aistrope, & Snella 2012).

The $CHADS_2$ (Congestive heart failure, Hypertension, Age >75 years, Diabetes mellitus previous Stroke/transient ischemic attack (TIA) is another risk stratification score. When the $CHADS_2$ and the $CHA_2 DS_2$-VASc are compared, both predict an outcome of an acute stroke; however, the $CHA_2 DS_2$-VASc score predicts a higher percentage of high stroke risk scores using more common stroke risk factors and identifies true low risk patients (Lane & Lip, 2012). Therefore, the $CHA_2 DS_2$-VASc tool increases the number of patients with AF who are eligible for OAC (Padjen et al., 2013).

Nonvalvular AF is defined in the ACC/AHA/Heart Rhythm Society (HRS) 2014 guidelines as AF in the absence of the following: rheumatic mitral stenosis, mechanical or bio prosthetic heart valve, or mitral valve repair (January et al., 2014). The introduction of direct oral anticoagulants (DOACs) has expanded the therapeutic options for primary and secondary stroke prevention in patients with nonvalvular AF.

With the use of OAC there also comes an increased risk for bleeding and in some cases death. The HAS-BLED score (Table 1) is a simple bleeding score that was developed and first validated by the EuroHeart survey and then in multiple independent populations (Lip, 2012). The HAS-BLED score ranges from 0 to 9, with scores of ≥3 indicating a high risk of bleeding. The HAS-BLED score should not be used to exclude patients from OAC, rather individuals with a HAS-BLED score of 2 or higher should be closely monitor for bleeding following the initiation of OAC. Risk factors for bleeding that are correctable should be addressed and modified where possible (Palomaki et al., 2012).

Table 1

Stroke Risk Score and Bleeding Risk Score

CHA_2DS_2-VASc	Score	HAS-BLED	Score
Congestive heart failure/Left ventricular dysfunction	1	Hypertension	1
Hypertension	1	Abnormal renal or liver function	1 or 2
Age ≥ 75 years	2	Stroke	1
Diabetes mellitus	1	Bleeding tendency of predisposition	1
Previous Stroke/transient ischemic attack/Thromboembolism	2	Labile International Normalized Ratio (INR) (if on warfarin)	1
Vascular disease (prior myocardial infarction, peripheral artery disease, or aortic plaque)	1	Age >65	1
Age 65-74 years	1	Drugs (aspirin or NSAIDS or alcohol excess/abuse)	1
Sex category (female sex)	1		
Maximum score	9	Maximum Score	9

Table 1. Stroke risk and bleeding risk scores. Adapted from "Predicting the outcomes of acute ischaemic stroke in atrial fibrillation: The role of baseline CHADS2, CHA_2DS_2-VASc and HAS-BLED score values" by Padjen et al., 2013, *ActaCardiologica, 68*(6), 590-596. Copyright 2013 by *ActaCardiologica*.

There are now several different OAC options for individuals with nonvalvular AF who score a CHA_2 DS_2-VASc score of > 2 and have low hemorrhagic complications. Vitamin K antagonists (VKA), warfarin, with a goal INR range of 2-3, and the direct oral anticoagulants (DOACs) dabigatran, rivaroxaban, apixaban, and edoxaban have been approved for prevention of CVA in individuals with nonvalvular AF (Meschia et al., 2014). All available anticoagulants have been shown to prevent stroke effectively. One advantage to the DOACs is a decreased risk for intracerebral hemorrhage (ICH). Another advantage is the shorter half-life of 5-17 hours compared to 20-60 hours with warfarin (Ansell, 2016; Moroti & Goldstein, 2016; Verheugt, 2013). Oral anticoagulant therapy is superior to antiplatelet therapy when providing prevention of stroke in the setting of AF (Baker, Wilsmore, & Narasimhan, 2016).

Reversal agents are available or under development for VKA and DOACs. Vitamin K will reverse VKA-induced coagulopathy, but it requires 12-24 hours for results to be seen. Fresh frozen plasma (FFP) and prothrombin complex concentrates can be used to reverse VKA-related bleeding (Ansell, 2016). Idarucizumab is the approved reversal agent for the direct thrombin inhibitors, dabigatran. Dexanetalfa is a reversal agent underdevelopment for the factor Xa inhibitors, rivaroxaban, apixaban, and edoxaban. Ciraparantag is a reversal agent underdevelopment for direct thrombin inhibitors and factor Xa inhibitors (Ansell, 2016). An individual experiencing non-urgent bleed such as gastrointestinal bleed that responds to fluid resuscitation or need for emergent surgery can simply discontinue the DOAC which will permit rapid reversal. Patients experiencing a major bleeding event such as trauma, overdose, or need for urgent intervention while on DOACs should receive fluid resuscitation, packed red blood cell transfusion, and platelet transfusion. Hemodialysis may reverse dabigatran. For an individual that has ingested a DOAC within two to three hours prior to the time of treatment, gastric lavage with activated charcoal is recommended (Ansell, 2016). Providers also need to consider an individual's kidney function when initiating anticoagulation therapy; DOACs are metabolized through the kidneys and those with poor kidney function have an increased risk of anticoagulant associated bleeding (Morotti & Goldstein, 2016).

Statement of the Problem

Oral anticoagulation therapy has been shown to reduce stroke risk by 64% in individuals with AF (Meschia et al., 2014). Unfortunately, there is an underuse of OAC by providers caring for individuals over the age of 65 with AF, particularly those perceived to be at risk for falls (Donzé et al., 2012; Jacobs, Billett, Freeman, Dinglas, & Jumaquio, 2009; Khan, Huang, & Datta, 2016). Studies have demonstrated only 55% of individuals who have AF and meet the criteria are being prescribed OAC (Ogilvie, Newton, Welner, Cowell, & Gregory, 2010). The impact of a stroke affects not only the individual, but their family related to costs as well as the healthcare system as a whole related to the number of resources this stroke victim will likely utilize. The indirect costs include productivity loss due to a premature death, disability, and the informal caregiving by family members.

Purpose of the Project

The purpose of the practice change DNP project is to increase the number of healthcare providers prescribing OAC in the outpatient setting among individuals who are age 65 or older, have a known history of AF, and a recent diagnosis of cerebral vascular accident (CVA) or transient ischemic attack (TIA). The role of OAC management typically falls to the patient's primary care provider or cardiology provider. By utilizing stroke and bleeding risk stratification schemes the decision to initiate OAC is simplified. Stroke prevention is key due to the increased risk of reoccurring strokes in individuals with AF and history of a TIA and/or CVA (Esenwa & Gutierrez, 2015).

Clinical Practice Question

Why do providers inconsistently prescribe OAC to patients with AF who are at risk for falls despite guideline recommendations? Several studies provide evidence that "fall risk" is not a contraindication to OAC (Banerjee, Clementy, Haguenoer, Fauchier, & Lip, 2014; Donzé et. al, 2012; Garwood & Corbett, 2008; Sellers & Newby, 2011) and use would improve patient outcomes by decreasing the risk for embolic stroke or ischemic events. Providers may be hesitant to initiate OAC in individuals who are considered at risk for falls due to the possible hemorrhagic complications, including ICH following a fall in the presence of OAC, lack of availability to reversal agents for some of the newer DOACs, or a previous patient experience with a poor outcome (Banerjee et al., 2014;Gattellari, Worthington, Zwar, & Middleton, 2008; Man-Son-Hing, Nichol, & Lau, 1999). According to Man-Son-Hing et al., (1999) an individual taking warfarin would have to fall 295 times in one year before the risk of being on the anticoagulant would outweigh the benefits. Providers should consider the risk of stroke compared to the risk of bleeding when recommending OAC and referring to a stroke and bleed risk model like the CHA_2DS_2-VASc score of > 2 and a HAS-BLED score of > 2 (Lane & Lip, 2012; Padjen et al., 2014).

CHAPTER 2: Review of Literature

A review of the literature identifies a range of factors associated with the underuse of OAC in older adults with AF. For this review, only studies focusing on AF and the use of OAC in individuals 65 and older were included due to existing gaps in the literature surrounding this topic. Two online databases, CINAHL and PubMed, were searched for research articles published after 2006 using the following key search terms: anticoagulation, warfarin, aspirin $CHADS_2$ score, CHA_2DS_2 -VASc score, HAS-BLED, elderly, falls, older persons, atrial fibrillation, bleeding, physical activity, education, stroke, use, fall risk, and shared decision making. Articles containing the following inclusion criteria were selected: (a) both AF and OAC in adults 65 years and older; (b) the studies collected included randomized controlled trials , retrospective analyses, observational studies, longitudinal study designs, meta-analysis, qualitative analysis, focus groups or surveys; (c) the findings included AF and OAC; fall risk and OAC; incident of bleeding and AF; $CHADS_2$ score and AF; CHA_2DS_2 -VASc score and AF; HAS-BLED and AF; and the effects of using/not utilizing OAC in the setting of AF; (d) date of publication span from 2006-2016; (e) published in English; (f) included all races; and (g) included both female and male human subjects. Studies containing the following exclusion criteria were not used: (a) non-English articles; (b) articles published before 2006; (c) articles not related to OAC or AF in the older adult. Using the above criteria,167 journal articles were obtained for review. Additional references were obtained through review of references from articles obtained and practice guidelines. Three practice guidelines and 20 articles were reviewed. Eleven studies did not meet inclusion criteria leaving nine articles and three practice guidelines for this review.

Nine studies and three practice guidelines published from 2007-2016 were identified. Two studies took place in the United States (Aakreet al., 2014; Jacobs, Billet, Freeman, Dinglas, & Jumaquio 2009); one study took place in Saudi Arabia (Al-Turaiki et al., 2016); one in Serbia (Padjen et al., 2013); one in Scotland (Abdul-Rahim, Wong, McAlpine, Young, & Quinn, 2014); two in Australia (Baker, Wilsmore, & Narasimhan, 2015; Gattellari, Worthington, Zwar, & Middleton, 2007); one in France (Banerjee, Clementy, Haguenoer, Fauchier, & Lip 2014);and one study took place in Europe, Japan, North America, China and intercontinental (Hart, Pearce, & Aguilar, 2007). Two of the three practice guidelines were from the United States (Furieet al., 2012; January et al., 2014), and the third was from Europe (Kirchhof et al., 2016). Two studies were cross sectional (Abdul-Rahimet al., 2014; Al-Turaiki et al., 2016), one study was longitudinal, (Aakre, et al., 2014), four studies were retrospective (Baker et al., 2015; Banerjee et al., 2014; Jacobs, 2009; Padjen et al., 2013), one study was a survey (Gattellari et al., 2007), and one study was a systematic review with meta-analysis (Hart et al., 2007). Three clinical practice guidelines were also reviewed (January et al., 2014; Kirchhof et al., 2017; Meschia et al., 2014).

Six of the nine studies had large numbers of subjects increasing their strength and generalizability (Aakre et al., 2014; Abdul-Rahim et al., 2014; Baker et al., 2015; Banerjee et al., 2014; Gattellari et al., 2007; Hart et al., 2007). The subjects in the study by Gattellari et al. (2007) were family physicians and addressed the psychological barriers to prescribing OAC. In one study subjects were obtained from a single registry where risk factors may have been under diagnosed (Aakre et al., 2014). Another study had a small sample size in a single site register based observational setting (Padjen et al., 2013). The subjects were from a single center and there was no discernment between non-valvular and valvular AF in the medical records (Padjen et al., 2013). The meta-analysis was the largest summarizing study of its kind evaluating the effects of antithrombotic therapy in stroke prevention among those with non-valvular AF (Hart et al., 2007). The meta-analysis included 29 RCTs and nine double-blind trials. Methodological features varied in the meta-analysis.

Sample Characteristics

A total of 42,361 subjects participated in these eight studies that support practice guidelines using OAC in individuals that had AF and had been screened by a stroke risk model and bleeding model (Aakre et al., 2014; Abdul-Rahimet al., 2014; Al-Turaiki et al., 2016; Baker et al., 2007; Banerjee et al., 2014; Hart et al., 2007; Jacobs et al., 2007; Padjen et al., 2013). Abdul-Rahim et al. (2014), Al-Turaiki et al. (2016), Banerjee et al. (2014), and Jacobs et al. (2007) were the only four studies that reported the sex of the participants. A total of 596 physician subjects participated in survey reporting AF management (Gattellari et al., 2007).

A cross sectional study by Abdul-Rahim et al. (2014) reported 6736 men with chronic AF, aged 65 years and older and 8001 women aged 65 years and older with AF. The meta-analysis by Hart et al. (2007) consisted of 28,044 participants with AF with average age 71 years. Some of the trials in the Hart et al. (2007) meta-analysis included individuals with previous stroke or TIA. Lastly, there were three clinical practice guidelines included that recommended the use of OAC for management of stroke prevention in individuals with AF but did not have any participants (January et al., 2014; Kirchhof et al., 2017; Meschia et al., 2014)

Risk Assessment

Eight of the nine studies (Aakreet al., 2014; Abdul-Rahimet al., 2014; Al-Turaiki et al., 2016; Baker et al, 2015; Banerjee et al., 2014; Hart et al., 2007; Jacobs et al., 2007; & Padjen et al., 2013;) used a $CHADS_2$, or a CHA_2DS_2-VAS_c score and five of the nine studies used HAS-BLED to evaluate participants' risk of a stroke and bleeding (Abdul-Rahim et al., 2014; Al-Turaiki et al., 2016; Baker et al., 2015; Banerjee et al., 2014; & Padjen et al., 2013). The duration of the studies ranged from one to 14 years. The European Society of Cardiology recommends utilizing the CHA_2DS_2-VASc score to estimate stroke risk in patients with AF and supports the use of HAS-BLED to evaluate for bleeding risk. These stroke risk stratification schemes for individuals with AF were first developed in 1990 in small cohort studies and were further developed and later validated in larger populations (Kirchhof et al., 2016). The ACC compared the $CHADS_2$ score with the CHA_2DS_2-VAScscore for non-valvular AF and found it has a broader score (January et al., 2014). The AHA/ASA recommended using $CHADS_2$ score for patients with AF. This risk stratification scheme is validated by sufficient evidence from randomized control studies (Furie et al., 2012).

Results of Intervention

The two cross sectional studies (Abdul-Rahim et al., 2014; Al-Turaiki et al., 2016;) showed a high risk for stroke using the CHA_2DS_2-VAS_c with the following scores 5, 2, and > 2. A high-risk the CHA_2DS_2-VAS_c score is considered > 2. According to Hart et al. (2007), there were 12 trials that randomized placebo or control treatment in individuals who had a history of stroke or TIA, and the results showed average stroke rate at 4.1% per year among those on OAC and 13% per year among those who were not treated. The retrospective observational study Jacobs et al. (2007) reported 85% of patients ≥ 65 years with chronic nonvalvular AF with low hemorrhagic risk were prescribed warfarin. Those with fall and/or dementia had a 45% mortality rate. The retrospective study by Banerjee et al. (2014) showed no statistical difference in the number of ischemic strokes or thromboembolism or mortality amongst individuals who had been anticoagulated or nonanticoagulated regardless of the fall history. The increased risk stratification scores were likely due to other comorbidities that influence $CHA_2DS_2\text{-}VAS_c$ score. The retrospective study by Padjen et al. (2013) showed the HAS-BLED score had an independent predictive value of symptomatic ICH regardless if treatment for an ischemic stroke was conservative or treated with a thrombolysis agent. A retrospective study by Baker et al. (2015) found OAC prescriptions increased from 50.9% to 64.1% in one year. This increase was attributed to the increase in DOAC being prescribed.

According to a meta-analysis by Hart et al. (2007) dose adjusted warfarin was associated with a 64% reduction in stroke among those in six randomized trials with AF. Unfortunately, no stroke risk score was included in these trials. The survey by Gattellari et al. (2007) reported family physicians feared bleeding and personal patient experience with a bleeding. Next, family physicians felt responsible if their patient experienced ICH while OAC for AF. Physicians chose other treatments such as aspirin or clopidogrel instead of warfarin when a patient was experiencing bleeding, such as nose bleeds, or had preventable bleeding risks like treated peptic ulcers and falls.

The European stroke prevention guidelines recommend using OAC in men with a $CHA_2DS_2\text{-}VAS_c$ score of 2 or more and a score of 3 or more in women. The European stroke prevention guidelines also recommend against withholding OAC therapy when an individual has a high bleeding risk (Kirchhof et al., 2016). The ACC showed the $CHA_2DS_2\text{-}VAS_c$ score included more risk factors female sex, 65-74 years of age, and vascular disease. With the

$CHA_2DS_2\text{-}VAS_c$ score a woman is not able to achieve score of 0 thus identify higher risk females that may have been underscored using the $CHADS_2$ score (January et al., 2014). The AHA/ASA recommended initiating treatment for a $CHADS_2$ score ≥ 2 (Furie et al., 2012).

CHAPTER 3: Theoretical Framework

The ACE Star Model of Knowledge Transformation (Star Model) has been used in clinical and education settings to support evidence-based practice. This model explains how clinical practice guidelines are the solution for moving research findings into everyday practice. Healthcare is then improved as new evidence-based knowledge is transformed through the five stages of the Kathleen Stevens' ACE Star Model as cited by Dang et al. (2015). The five-point Star Model represents five different stages of knowledge transformation (Table 2).

Table 2

ACE Star Model

Stages of Knowledge Transformation	
Discovery	Primary research studies generate new knowledge
Evidence Summary	A systematic review of all the available knowledge
Translation to Guidelines	Combine evidence base and expertise knowledge to provide recommendations
Practice Integration	Factors that affect integration of change to reflect the strength of the evidence
Process, Outcome, Evaluation	Evidence-based practice is evaluated in regard to the patient's health outcomes, satisfaction, and efficacy of care and health policy

Table 2. ACE Star Model. Adapted from "Models to guide implementation and sustainability of evidence-based practice," by Dang et al., 2015, Evidence based practice in nursing & healthcare a guide to best practice, 3rd ed., pp. 274- 315. Copyright 2015 by Wolters Kluwer

The first stage of the Star Model identifies an area of discovery where new knowledge generates in primary research studies; in this project, the underuse of OAC in individuals who are over the age of 65 with AF. The second stage, evidence summary, is a systematic review of all the literature identifying a range of factors associated with the underuse of OAC in older adults with AF. The third stage combines evidence base and expertise knowledge to provide recommendation that translate to guidelines. Clinical practice guidelines recommend individuals with AF who have a CHA_2DS_2-VASc of > 2 or $CHADS_2$ score ≥ 2 should be placed on OAC provided they do not have a contraindication (January et al., 2014).

The forth step, practice integration, included factors of change to reflect the strength of the evidence. Integration into practice began in August 2017 with an educational in-service to hospitalists and cardiology providers affiliated with CaroMont Regional Medical Center (CRMC) that included the CHA_2DS_2-VASc stroke score, the HAS-BLED bleeding score, and their meanings. A review of clinical practice guidelines for stroke and the use of OAC in older adult patients with AF did take place as well as a discussion on patient scenarios that were not considered a contraindication for initiating OAC, including falls risk and dementia.

The fifth stage of the Star Model includes the impact of evidence-based practice including the process, outcome, and evaluation. The process of hospitalist buy in was crucial to the project's success. Reminding providers of stroke practice guidelines gave support and credibility to my project. Following the educational in-service 100% of those patients who were eligible were offered a prescription for OAC. Indicating that the in-service had a positive impact on provider practice and patients' health outcome in relationship to follow clinical practice guidelines. Following the implementation period, the project and interactions with staff was evaluated. Over all the project was successful due to providers following practice guidelines and offering medication to eligible patients to help reduce a risk factor of stroke.

CHAPTER 4: Methodology

Setting and Participants

The setting for this DNP project was CaroMont Health a not-for-profit independent healthcare system in Gastonia, North Carolina. This healthcare system includes a 435-bed hospital, specialists, primary care offices, urgent care locations, and emergency departments throughout the region (http://www.caromonthealth.org/). The subjects for this DNP project included cardiology providers and the primary care providers within the CaroMont Health Care System. These two groups are most often responsible for initiating OAC in the outpatient setting following hospital discharge of patients with AF who were admitted for a CVA or TIA.

Intervention

An in-service on high stroke risk in the setting of AF and previous TIA/CVA was given to the hospitalists and cardiology providers at CaroMont Regional Medical Center (CRMC). Information used in the presentation came from evidence-based research articles and clinical practice guidelines to provide documentation concerning when to initiate OAC, and to show that a fall risk and supervised dementia patients are not contraindications to therapy. This information reinforced the need for change when it came to initiate OAC in older adults with AF. Information provided during the discussion included the CHA_2DS_2-VASc score and its meaning and how the inpatient neurology service at CRMC provide recommendations regarding OAC. Provider to provider follow up education sessions were given to those identified with an eligible patient on their service. The presentation detailed the timing of OAC initiation was dependent on the size of a stroke. If a stroke was small vessel in origin OAC would be initiate in the hospital, those medications typically include apixaban 5mg twice a day depending on renal function or warfarin dosed by pharmacy. If a large vessel stroke were to be identified initiation of OAC would be seven to ten days following the stroke. In patients with large vessel strokes, a repeat CT scan of the head may be recommended prior to the initiation of OAC. An algorithm utilizing the HAS-BLED bleeding risk score and CHA_2DS_2-VASc stroke risk score was provided during the presentation to aid in decision-making surrounding OAC (Appendix 1). The use of OAC has been shown to improve patient outcomes by decreasing the risk for embolic stroke or ischemic events (Garwood & Corbett, 2008; January et al., 2014; Kirchhof et al., 2017; Sellers & Newby, 2011).

The patient population of interest included those patients 65 years of age and older who had been diagnosed with a CVA or TIA while hospitalized at CRMC with a history of AF, were not on OAC therapy, and had received a neurology consult during their hospitalization. The hospitalists providing medical management do not typically initiate OAC therapy in the inpatient setting; however, they are responsible for providing a hospital discharge summary with specific OAC recommendations that primary care providers (PCP) and outpatient cardiology providers utilize at follow up appointments. The hospitalists were asked to include the CHA_2DS_2-VASc score and HAS-BLED scores in the discharge summary along with the recommendation for when to start OAC in the outpatient setting based on neurology's recommendations. The cardiology providers were presented with the same inform as well and reminded that every patient should be considered on an individual basis to whether they are eligible for treatment. Fall risk and dementia should not be automatic contraindications. The majority of inpatient cardiology providers include a CHA_2DS_2-VASc scores in their notes on patients with AF.

Data Collection

The EMR was used to identify those patients age 65 or older, admitted to CRMC from July 2016 to September 2016 and from July 2017 to September 2017 with a diagnosis of AF and CVA/TIA, and who were eligible for OAC. A review of medical records from the hospital, primary care, and cardiology outpatient settings using EPIC identified whether these patients received a prescription for an OAC at time of discharge or during a hospital follow up appointment. Addition data used to score the CHA_2DS_2-VASc score and HAS-BLED score was collected (Table 1), in addition to descriptors of the patient population race, body mass index (BMI), current smoking, obstructive sleep apnea, dyslipidemia, and a history of neck radiation.

All patient information, including medical record numbers to allow for tracking prescriptions over 30 days, was stored on an encrypted flash drive that was password-protected and remained at CRMC at all times. Once the follow up data was obtained, a random number replaced the medical record number to de-identify patient information.

Analysis Plan

The principal quantitative outcome was the rate (or percentage) of those patients who were eligible for OAC in the outpatient setting and actually received a prescription for an OAC. Due to a small sample size, only descriptive statistics computed using data from each period in 2016 and 2017 were used to describe these two subsamples. Standard deviations and means were calculated for continuous variables such as age, CHA_2DS_2-VASc score, and HAS-BLED score. Frequencies and percentages were used to describe categorical variables.

CHAPTER 5: Results

A total of 27 patients were included in the analysis, 15 patients in 2016 and 12 patients in 2017. In 2016, 53% (n=8) received prescriptions for warfarin, 13% received apixaban (n=2), and 6% received rivaroxaban (n=1). One patient refused OAC and another patient's family refused as the patient transitioned to hospice. Overall 87% (n=13) patients who were eligible for OAC therapy were offered prescriptions by providers. Two patients were not offered OAC therapy by providers due to fall risk and noncompliance. In 2016, only nine of the 15 providers that discharged eligible patients mentioned neurology’s recommendations when to start OAC therapy. In 2017 58% (n=7) received prescriptions for apixaban, 33% (n=4) for warfarin, and one refused OAC therapy. Overall, 100% (n=12) patients who were eligible for oral anticoagulation therapy were offered prescriptions by providers. Of those 12 providers, 10 received education regarding the stroke and bleeding risk scores. In 2017, 11 of the 12 providers that discharged eligible patients mentioned the stroke/bleeding risk score or neurology's recommendation when to start OAC therapy.

The demographics and clinical characteristics of patients are included in Table 3. One-hundred percent of those eligible for OAC therapy were Caucasian in 2016 and 2017. There were less females, 67% in 2016 compared to 83% in 2017. The population was older in 2016 (mean age 82.2 years, [SD 7.66]) compared to 2017 (mean age 79.7 years [SD 9.86]). Other comorbidities such as dementia were equal among the two groups. Prior falls were more common in 2016, 33% compared to 8% in 2017. Obstructive sleep apnea was present in 6% in

2016 compared to 16% in 2017. No one used tobacco products in 2016 compared to 8% in 2017. Forty percent were obese with a BMI greater than 30 in 2016, compared to 58% in 2017.

Table 3

Demographic and Clinical Characteristics

	2017	2016
Age years mean (SD)	79.7 (9.86)	82.2 (7.66)
Female sex, n (% female)	10 (83%)	10 (67%)
Male sex, n (% male)	2 (17%)	5 (33%)
Race	12 (100%) Caucasian	15 (100%) Caucasian
Antiplatelet therapy not on admission	8 (67%)	11 (73%)
Aspirin	4 (33%)	2 (13%)
Clopidogrel	0%	0%
Aspirin &Clopidogrel	0%	1 (6%)
Medication noncompliance	0%	2 (13%)
Falls	1 (8%)	5 (33%)
Dementia	2 (16%)	2 (13%)
OSA	2 (16%)	1 (6%)

There were no significant differences observed in the CHA_2DS_2-VAS_c scores between the two groups (mean score 6.47 [SD 0.51]) compared to the 2017 group (mean score 7 [SD 1.25]). There was a higher HAS-BLED score the 2016 patient group (mean score 4 [SD .846]) compared to 2017 group (mean score 3.25 [SD 0.62]).

In 2016, 6% of patients had a prior clinical relevant non-major bleed compared to 16% in 2017 (Table 4). Prior to admission, 87% of patients were on an antiplatelet medication in 2016 compared to 33% in 2017.

Table 4

Stroke and Bleeding Risk Factors (n= 27)

Stroke Risk Factors	2017 (n=12)	2016 (n=15)
CHA_2DS_2-VASc mean	Mean 7.08	Mean 6.47
Standard Deviation (SD)	SD (0.51)	SD (1.25)
Congestive heart failure/LV dysfunction	6 (50%)	9 (60%)
Hypertension	12 (100%)	13 (87%)
Age ≥ 75 years	8 (67%)	13 (87%)
Diabetes mellitus	4 (33%)	7 (47%)
Stroke/TIA/TE	12 (100%)	15 (100%)
Vascular disease (prior MI, PAD, or aortic plaque)	4 (33%)	3 (20%)
Aged 65-74 years	4 (33%)	2 (13%)
Sex category (female sex)	10 (83%)	10 (67%)
Bleeding risk factors	2017 (n=12)	2016 (n=12)
HAS-BLED Mean	Mean 3.25	Mean 4
Standard Deviation (SD)	SD (0.62)	SD (0.85)
Hypertension	12 (100%)	13 (87%)
Abnormal renal or liver function	1 (8.3%)	2 (13%)
Stroke	12 (100%)	15 (100%)
Bleeding tendency of predisposition	2 (16%)	1 (6%)
Labile International Normalized Ratio (INR)s (if on warfarin)	0	0
Drugs Aspirin or NSAIDS	9 (75%)	13 (86%)
Alcohol excess/abuse	0	0

Table 5 shows stroke and bleeding risk scores for the patients included in this practice improvement project. In 2016, 67% of patient had a higher stroke risk score when compared to the bleeding risk score. Only 33% had a higher bleeding risk score compared to stroke risk score. In 2017, 92% of patients had a higher stroke risk score compared to bleeding risk score.

Table 5

Analysis of Bleeding and Stroke Risk

	CHA_2DS_2-VASc score (stroke risk % per year)								
Has-Bled score (bleeding risk % per year)	0 (.84)	1 (1.79)	2 (3.67)	3 (5.75)	4 (8.18)	5	6 (11.0)	7 (11.0)	8 (11.0)
2016 Patients (15)									
0 (1.2)									
1 (2.8)									
2 (3.6)									
3 (6.0)					N=1		N=3	N=1	
4 (9.5)							N=1	N=2	N=2
5 (12.5)					N=1		N=1	N=2	
6 (12.5)									N=1
2017 Patients (12)									
0 (1.2)									
1 (2.8)									
2 (3.6)									
3 (6.0)							N=1	N=7	N=2
4 (9.5)								N=1	
5 (12.6)								N=1	
6. (12.6)									

CHAPTER 6: Discussion

The number of eligible patients who were offered prescriptions for OAC increased from 87% in 2016 to 100% in 2017. This increase indicates that the intervention resulted in an effective practice change among providers. Of the 12 providers discharging patients with stroke and AF, 100% mentioned the stroke risk/bleed risk scores or neurology recommendations in their discharge notes. Two of the providers, a cardiologist and critical care internist, did not receive education regarding the implementation project; however, the cardiologist did make mention of the stroke risk score in his note and the critical care internist did mention the plan the neurology team recommended regarding anticoagulation management.

Eight of the 15 patients in 2016 were started on warfarin compared to DOACs in three patients. Of the 11 patients who accepted the prescription for OAC therapy in 2017, nine received prescriptions for apixaban to fill at discharge, and two received prescriptions to start warfarin later. Physicians are also becoming more familiar with the stroke risk scoring methods which may also lead to confidence in prescribing of OAC therapy. Those on the cardiology service are already using the $CHA_2 DS_2$-VASc stroke risk score in their notes regarding individuals with atrial fibrillation.

The majority of patients in both groups, 2016 and 2017, were women, while the incident of AF is higher in males the risk of death in females with AF is higher (Kirchhof et al., 2016). Women are less likely to receive therapy for rate control associated with AF or specialist care. They also tend to be older with more comorbidities compared to men (Kirchhof et al., 2016).

Using the $CHA_2 DS_2$-VASc stroke risk will help to identify more eligible women for anticoagulation therapy. In 2016 & 2017, 100% of the patients were Caucasian females. These results did not reflect past epidemiological research in which African American patients are known to have a higher incidence of all strokes compared to Caucasians (Meschia et al., 2014).

Limitations

There are several limitations to this project. The population was drawn from a specific institution, resulting in a small sample size. Similarly, the enrollment period was only three months. Yet another limitation of the project was that it involved only patients who were admitted to the hospital and comorbidities may be higher in this population. There is a possibility that eligible patients may have been missed if the hospital neurology team was not consulted during their hospitalization. Also, if coding for a stroke or TIA was not listed in the EMR, potential patients may have been missed. Stroke and bleeding risk score education only encompassed hospitalists working day shift. The intensive care internists and nocturnist hospitalists were not educated regarding the practice improvement due to low expectations that they would write a discharge summary. Lastly, most stroke patients in this project had small vessel strokes thus, OACs were started in the hospital setting or on day of discharge rather than waiting a week and initiating in the outpatient setting. The number of providers offering OAC prescriptions may not have been as high in the outpatient setting because of this.

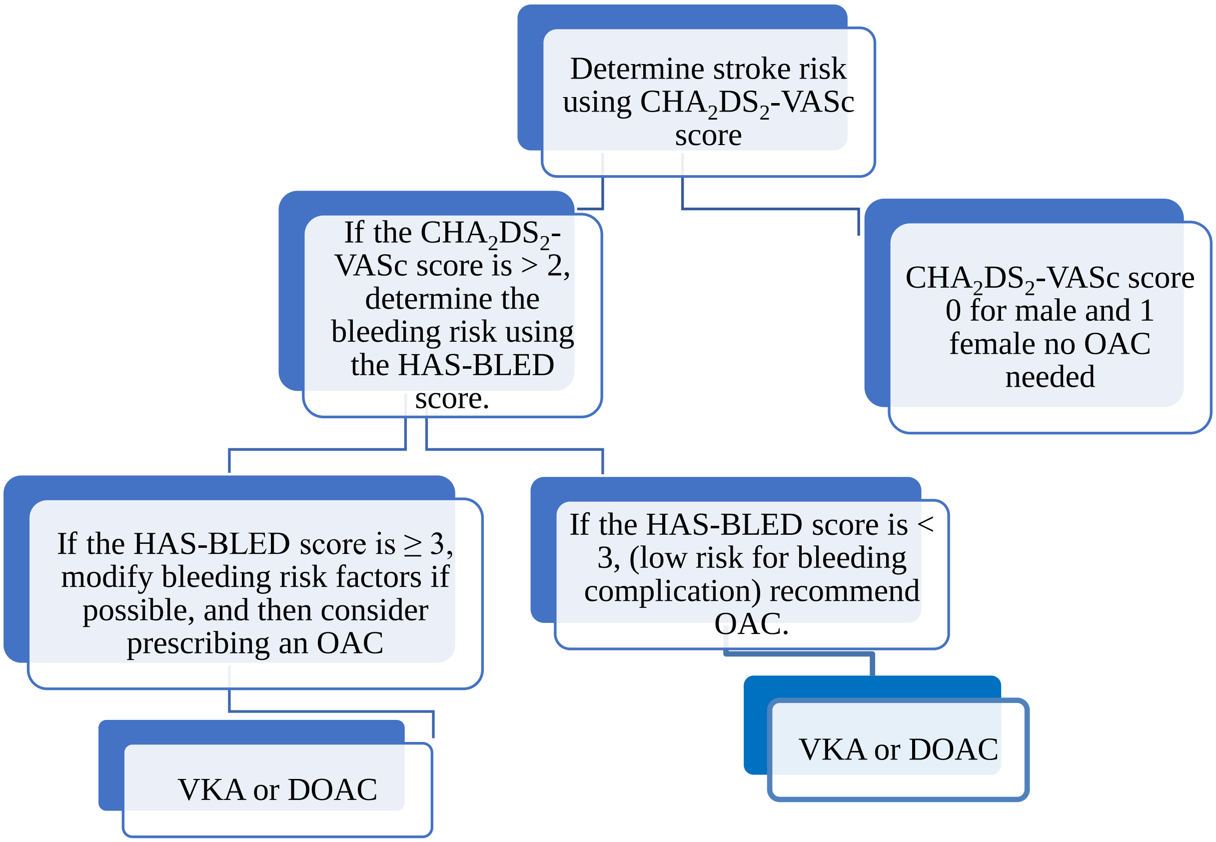
CHAPTER 7: Implications for Practice

Practice improvement for correcting the underuse of OAC was seen following the discussion with providers regarding practice guidelines, stroke and bleeding risk scores, an anticoagulant algorithm (Appendix 1), and recommendations made by neurology. The number of patients discharged with prescriptions for OAC increased. By using the Anticoagulant Algorithm (Appendix 1), providers can identify who needs therapy. Other providers in the health care system such as intensivists, nocturnal hospitalists, and primary care providers would benefit from this education. Continued effort by those discharging patients to include neurology's recommendations when to initiate OAC therapy on a specific date, dosing of medications, stroke risk score, and bleeding risk score in their discharge summary provides support to those in the outpatient setting initiating OAC and to those in the inpatient setting to initiate during the hospitalization or at discharge when appropriate. Recognizing high risk stroke patients with non-AF by using the CHA_2DS_2-VASc would increase the number of patients prescribed OAC and improve cardioembolic stroke protection (Padjen et al., 2013; Hart, Pearce, & Aguilar, 2007).

CHAPTER 8: Conclusion

Following the education about the underuse of OAC therapy and practice guidelines there was an increase in prescribing OAC at time of discharge in patients with AF who had a stroke, rather than leaving it up to outpatient providers. Some hospitalists have since adopted the stroke risk scores as a part of their history and physical templates for stroke patients. While the sample size was small in this project the was potential for significant improvement in health outcomes. The risk for bleeding versus risk for stroke should be evaluated on an individual basis and the risk versus the benefits should be discussed with each patient. Including stroke and bleeding risk scores in hospital notes and discharge summaries identify those patients who are at a high risk for a stroke and to support the use of OAC.

Appendix: Anticoagulant Algorithm



REFERENCES

Aakre, C. A., McLeod, C.J., Cha, S.S., Tsang, T. S. M., Lip, G. Y. H., & Bernard, J. G. (2014). Comparison of clinical risk stratification for predicting stroke and thromboembolism in atrial fibrillation. *Stroke,* 45, 426- 431. doi:10.1161/STROKEAHA.113.002585

Abdul-Rahim, A. H., Wong, J., McAlpine, C., Young, C., & Quinn, T.J. (2014). Associations with anticoagulation: A cross-sectional registry-based analysis of stroke survivors with atrial fibrillation. *Heart (British Cardiac Society), 100,* 557- 562. doi:10.1136/heartjnl-2013-305267

Al-Turaiki, A. M. (2016). Assessment and comparison of CHADS2, CHA_2DS_2-VASc, and HAS-BLED scores in patients with atrial fibrillation in Saudi Arabia. *Annals of Thoracic Medicine, 11*(2), 146-150. doi: 10.4103/1817-1737.180026.

Ansell, J. E. (2016). Reversing the effect of oral anticoagulant drugs: Established and newer options. *American Journal of Cardiovascular Drugs: Drugs, Devices, and Other Interventions, 16*(3), 163-170. doi:10.1007/s40256-016-0162-7

Baker, D., Wilsmore, B., &Narasimhan, S. (2016). Adoption of direct oral anticoagulants for stroke prevention in atrial fibrillation. *Internal Medicine Journal*, *46*(7), 792-797. doi:10.1111/imj.13088

Banerjee, A., Clementy, N., Haguenoer, K., Fauchier, L., & Lip, G. Y. (2014). Prior history of falls and risk of outcomes in atrial fibrillation: The Loire Valley atrial fibrillation project. *The American Journal of Medicine, 127*(10), 972-978. doi:10.1016/j.amjmed.2014.05.035

Dang, D., Melnyk, B.M., Fineout-Overholt, E., Ciliska, D., DiCenso, A., Cullen, L., ...Stevens, K.R. (2015). Models to guide implementation and sustainability of evidence-based practice. In B.M. Melnyk &E. Fineout-Overholt (Eds.), *Evidence based practice in nursing & healthcare a guide to best practice* (3rd ed.) (pp. 274- 315). Philadelphia, PA: Wolters Kluwer

Donzé J., Clair, C., Hug, B., Rodondi, N., Waeber, G., Cornuz, J., &Aujesky, D. (2012). Risk of falls and major bleeds in patients on oral anticoagulation therapy. *The American Journal of Medicine*, *125*(8), 773-778. doi:10.1016/j.amjmed.2012.01.033

Esenwa, C., & Gutierrez, J. (2015). Secondary stroke prevention: challenges and solutions. *Vascular Health and Risk Management*, *11*, 437–450. doi.org/10.2147/VHRM.S63791

Furie, K. L., Goldstein, L. B., Albers, G. W., Khatri, P., Neyens, R., Turakhia, M. P., . . . Wood, K. A. (2012). Oral antithrombotic agents for the prevention of stroke in nonvalvular atrial fibrillation: A science advisory for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke, 43*(12), 3442-3453. doi:10.1161/STR.0b013e318266722a

Garwood, C. L., & Corbett, T. L. (2008). Use of anticoagulation in elderly patients with atrial fibrillation who are at risk for falls. *The Annals of Pharmacotherapy, 42*(4), 523-532. doi:10.1345/aph.1K498

Gattellari, M., Worthington, J., Zwar, N., & Middleton, S. (2008). Barriers to the use of anticoagulation for nonvalvular atrial fibrillation: A representative survey of Australian family physicians. *Stroke; a Journal of Cerebral Circulation, 39*(1), 227-230. doi:STROKEAHA.107.495036

Hart, R. G., Pearce, L. A., & Aguilar, M. I. (2007). Meta-analysis: Antithrombotic therapy to prevent stroke in patients who have nonvalvular atrial fibrillation. *Annals of Internal Medicine, 146*(12), 857-867. doi:146/12/857

Jacobs, L. G., Billett, H. H., Freeman, K., Dinglas, C., &Jumaquio, L. (2009). Anticoagulation for stroke prevention in elderly patients with atrial fibrillation, including those with falls and/or early-stage dementia: A single-center, retrospective, observational study. *The American Journal of Geriatric Pharmacotherapy, 7*(3), 159-166. doi:10.1016/j.amjopharm.2009.06.002

January, C. T., Wann, L. S., Alpert, J. S., Calkins, H., Cigarroa, J. E., Cleveland, J. C.Jr, . . . Sacco, R.L. (2014). 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society. *Journal of the American College of Cardiology, 64*(21), e1-76. doi:10.1016/j.jacc.2014.03.022

Khan, F., Huang, H., &Datta, Y. H. (2016).Direct oral anticoagulant use and the incidence of bleeding in the very elderly with atrial fibrillation. *Journal of Thrombosis and Thrombolysis, 42*(4), 573-578. doi:10.1007/s11239-016-1410-z

Kirchhof, P., Benussi, S., Kotecha, D., Ahlsson, A., Atar, D., Casadei, B., . . . Vardas, P. (2016). 2016 ESC guidelines for the management of atrial fibrillation developed in collaboration with EACTS. *European Heart Journal*, 37, 2893–2962. doi:10.1093/eurheartj/ehw210

Lane, D. A. & Lip, G.Y.H (2012). Use of the CHA_2DS_2-VASc and HAS-BLED scores to aid decision making for thromboprophylaxis in nonvalvular atrial fibrillation. *Circulation, 126,*860-865. doi: 10.1161/CIRCULATIONAHA.111.060061

Lip, G. Y. (2011).Implications of the CHA_2DS_2-VASc and HAS-BLED scores for thromboprophylaxis in atrial fibrillation. *The American Journal of Medicine, 124*(2), 111-114. doi:10.1016/j.amjmed.2010.05.007

Lip, G. Y. (2013). Stroke and bleeding risk assessment in atrial fibrillation: When, how, and why? *European Heart Journal, 34*(14), 1041-1049. doi:10.1093/eurheartj/ehs435

Lip, G. Y., Banerjee, A., Lagrenade, I., Lane, D. A., Taillandier, S., &Fauchier, L. (2012). Assessing the risk of bleeding in patients with atrial fibrillation: The Loire Valley atrial fibrillation project. *Circulation, Arrhythmia and Electrophysiology, 5*(5), 941-948. doi:10.1161/CIRCEP.112.972869

Man-Son-Hing, M., Nichol, G., Lau, A., & Laupacis, A. (1999). Choosing antithrombotic therapy for elderly patients with atrial fibrillation who are at risk for falls. *Archives of Internal Medicine, 159*(7), 677-685. doi: 10.1001/archinte.159.7.677 .

Meschia, J. F., Bushnell, C., Boden-Albala, B., Braun, L. T., Bravata, D. M., Chaturvedi, S.,…Creager, M.A. (2014). Guidelines for the primary prevention of stroke: A statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke, 45*(12), 3754-3832. doi:10.1161/STR.0000000000000046

Morotti, A.,& Goldstein, J.N. (2016). New oral anticoagulants and their reversal agents. *Current Treatment Options Neurology. 18*(47), 1-15. doi:10.1007/s11940-016-0430-5

.

Odum, L. E., Cochran, K. A., Aistrope, D. S., &Snella, K. A. (2012). The CHADS(2)versus the new CHA_2DS_2-VASc scoring systems for guiding antithrombotic treatment of patients with atrial fibrillation: Review of the literature and recommendations for use. *Pharmacotherapy, 32*(3), 285-296. doi:10.1002/j.1875-9114.2012.01023.x

Ogilvie, I. M., Newton, N., Welner, S. A., Cowell, W., & Lip, G. Y. (2010). Underuse of oral anticoagulants in atrial fibrillation: A systematic review. *The American Journal of Medicine, 123*(7), 638-645.e4. doi:10.1016/j.amjmed.2009.11.025

Padjen, V., Jovanovic, D. R., Leys, D., &Beslac-Bumbasirevic, L. (2013). Predicting the outcomes of acute ischaemic stroke in atrial fibrillation: The role of baseline CHADS2, CHA_2DS_2-VASc and HAS-BLED score values. *ActaCardiologica, 68*(6), 590-596. doi:10.2143/AC.68.6.8000006

Palomaki, A., Mustonen, P., Hartikainen, J.E.K., Nuotio, I., Kiviniemi, T., Ylitalo, A., …Airaksinen, K.E.J. (2016). Underuse of anticoagulation in stroke patients with atrial fibrillation-the FibStroke Study. *European Journal of Neurology, 23* 133-139. doi:10.1111/ene.12820

Sellers, M., & Newby, L. (2011). Atrial fibrillation, anticoagulation, fall risk, and outcomes in elderly patients. *American Heart Journal, 161*(2), 241-246. doi:10.1016/j.ahj.2010.11.002

Verheugt, F.W.A. (2013). Advances in stroke prevention in atrial fibrillation: Enhanced risk Stratification combined with the newer oral anticoagulants. *Clinical Cardiology, 36* (6), 312-322. doi: 10.1002/clc.22122