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# EARLY IDENTIFICATION AND INTERVENTION IN PATIENTS WITH ATRIAL FIBRILLATION USING AN IMPLANTABLE CARDIAC MONITOR TO SIGNIFICANTLY IMPROVE GUIDELINE-BASED ANTICOAGULATION THERAPY IN AN OUTPATIENT CARDIOLOGY CLINIC

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UNIVERSITY OF SAN DIEGO  
Hahn School of Nursing and Health Science  
DOCTOR OF PHILOSOPHY IN NURSING

EARLY IDENTIFICATION AND INTERVENTION IN PATIENTS WITH ATRIAL  
FIBRILLATION USING AN IMPLANTABLE CARDIAC MONITOR TO SIGNIFICANTLY  
IMPROVE GUIDELINE-BASED ANTICOAGULATION THERAPY IN AN OUTPATIENT  
CARDIOLOGY CLINIC

by

Lisa Alvarez

A dissertation presented to the  
FACULTY OF THE HAHN SCHOOL OF NURSING AND HEALTH SCIENCE  
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In partial fulfillment of the  
requirements for the degree  
DOCTOR OF PHILOSOPHY IN NURSING  
May 2019

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UNIVERSITY OF SAN DIEGO  
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DOCTOR OF PHILOSOPHY IN NURSING

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TITLE OF  
DISSERTATION:

Early Identification and Intervention in Patients  
with Atrial fibrillation using an Implantable Cardiac  
Monitor to Significantly Improve Guideline-Based  
Anticoagulation Therapy in an Outpatient  
Cardiology Clinic

DISSERTATION  
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## Abstract

The purpose of this research was to (a) examine the demographics of patients receiving care in an outpatient cardiology clinic, (b) describe the relationship between the atrial fibrillation (AF) and other variables (e.g., BMI), (c) examine the frequency and the length of time to AF diagnosis in patients implanted with an implantable cardiac monitoring (ICM) device, (d) observe provider patterns of treatment with oral anticoagulants (OACs), and (e) investigate documented considerations to either diagnose or rule out OSA in a group of outpatient AF patients in a cardiology clinic.

**Background:** AF is largely undiagnosed but can cause major morbidity and mortality. AF is the most prevalent sustained arrhythmia encountered in the emergency department, is frequently detected in those without a prior diagnosis of AF, and is the most common cause for stroke. All relevant guidelines suggest patients from intermediate to high risk for stroke should receive OAC; however, this therapy is prescribed in less than 55% of eligible patients. AF accounts for nearly 1 in 7 strokes and affects approximately 5.8 million people in the United States.

**Objectives:** The purpose of this study is to identify and intervene in patients with atrial fibrillation using an implantable cardiac monitor to significantly improve guideline-based anticoagulation therapy.

**Methods:** A retrospective database from an outpatient clinic in southern California was analyzed in this non-experimental study design; it comprised routinely-collected data on patients with ICMs implanted between June 1, 2014 and December 31, 2018. This study was designed to establish the incidence of AF using an ICM device (i.e., Medtronic LINQ) in the outpatient setting.

**Conclusions:** As evidenced by this study, most patients would not have been diagnosed with AF utilizing the shorter-duration monitoring devices typically used as the first line of treatment. Longer monitoring capabilities promise early identification of disease and reduction in morbidity for AF patients.

**Discussion:** The incidence of AF using an ICM (i.e., Medtronic LINQ) device in an outpatient clinic was 23.4% (63 out of 269 patients), similar to national studies stating that longer monitoring of cardiac rhythms increased the diagnosis of arrhythmias. Only 12.7% of detected AFs (11 out of 63 patients) occurred before 14 days, the maximum time available through the use of other, traditional monitoring devices in standard use; therefore, an alarming 87.3% of ICM-detected arrhythmias could have remained unidentified. This research observed a reduction of potential, highly-debilitating embolic stroke through detection as well as a lessened risk of all-cause mortality with OACs for AF patients without stroke prophylaxis; early identification and treatment is possible utilizing an ICM device.

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## Dedication

I dedicate this dissertation to my mother and father, Jo and Walter Ray Meads, for their guidance and strength through this long journey. You both believed in me when I did not believe in myself. You taught me to have strong character, provided encouragement, and a shoulder to cry on through the ups and downs.

I dedicate this dissertation to my children Kai Alvarez and Jett Alvarez. I strive to provide a positive role model for you and continue to try to make you proud of me.

Lastly, I dedicate this study to all the patients who have had life-changing embolic events from atrial fibrillation because they were not diagnosed earlier.

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## **Chapter 1**

### **Statement of the Problem**

The purpose of this study is to identify and to provide early intervention with patients at high risk for nonvalvular atrial fibrillation (AF) with implantable cardiac monitoring devices (ICM) and significantly improve treatment with guideline-based oral anticoagulation (OAC). AF affects 1% to 2% of the general population and the prevalence is increasing worldwide, due in part to the aging population (Colilla, Crow, Petkun, Singer, Simon, & Liu, 2013). This number is estimated to double by 2050 (Miyasaka, Barnes, & Gersh, 2006). The cost of care for patients with AF are substantial. Estimates range from \$6 billion to \$26 billion a year of which \$6 billion was attributed directly to AF and \$9.9 billion to other cardiovascular expenses (Mozaffarian, Benjamin, & Go, 2015). AF is often asymptomatic, paroxysmal, or both (Barbarossa, Guerra, & Capucci, 2014); therefore, the arrhythmia goes undetected until major complications arise and/or patients become disabled. In some cases, the diagnosis of thromboembolism/ stroke may be the first identification of AF. AF is associated with a four- to five-fold increase in risk for thromboembolism (Wolf, Abbott, & Kannel, 1991). Thromboembolism/stroke is a leading cause of long-term disability and can lead to irreversible harm such as memory loss, altered psychological status, speech/language difficulty, and disability/paralysis (Mozaffarian et al., 2015). Early identification and treatment of patients with AF are essential in decreasing devastating effects from thromboembolic disease. With the Internet, smart phones, and other new ways of detection, AF can be identified more frequently, but currently there are no protocols or guidelines to diagnosis this elusive arrhythmia. The inability to provide timely identification or diagnosis of AF is imperative and supports the purpose of this research study. The goal of this research project is to determine the most specific and accurate method(s) for the early

identification of AF; newer forms of detection have inaccurately provided noise where they are typically a warning and a way for further investigation by a licensed practitioner. When AF is symptomatic, detection is straightforward because the symptoms often include palpitations, syncope, chest pain, or shortness of breath. These symptomatic cases are typically diagnosed and treated quickly due to the patient's ailing complaints and presentation to the health care practitioner. Nonetheless, AF is most often asymptomatic and therefore is largely undiagnosed until the occurrence of major morbidity or mortality through thromboembolism or heart failure (HF). Improved guideline-based therapy could directly reduce the risk of a potential, highly debilitating thromboembolism in AF patients.

This study will commence with a description of the scope and significance of AF. A discussion ensues for more timely identification of AF with ICM and approaches for continued follow up for patients with AF. These sections will be followed by a review of the literature that support the rationale for this study.

### **Background and Significance**

The purpose of this research is to add knowledge to the early detection of AF and to assist in decreasing morbidity and mortality and advancing timelier treatment of AF with oral anticoagulants, procedures, and treatments using ICMs to identify arrhythmias. Currently, no protocols or guidelines exist on the diagnosis of AF or the type of monitoring device to use. Presently, the provider selects the monitoring device based on comfort and knowledge of the products. Monitors vary in duration of surveillance for cardiac rhythms, from seconds up to 3 years. As the population ages, the prevalence of AF increases as does the sequela of AF's morbidity and mortality effects. The U.S. population aged 65 years and over grew from 35.0 million in the year 2000 to 49.2 million in the year 2016; expectations are for continued growth

in this population sector (U.S. Census Bureau, 2017). The median age in the United States is expected to grow from 38 years old today to 43 years old by 2060 (U.S. Census Bureau, 2018).

AF is the most prevalent sustained arrhythmia encountered in emergency departments (EDs) and outpatient clinics; 3.6% to 7.0% of general emergency visit (Coll-Vinent, Malagon et al., 2007). Currently there is no implementation of common guidelines at various care levels to improve AF treatment (Coll-Vinent, Pacheco et al., 2007). AF is defined by the American Heart Association as a heart arrhythmia where the upper chambers of the heart (the atria) beat irregularly instead of beating effectively to move blood into the ventricles (American Heart Association, n.d.). AF can decrease the heart's pumping capacity by as much as 30% (Harvard Medical Publications, 2018). When blood does not move effectively, it can become stagnant and thickened to form thrombus (i.e., clot) that could lead to dangerous thromboembolic events. The blood cells adhere to each other and form clots in the left atrial appendage (LAA) of the heart (Blackshear, & Odell, 1996). When the thrombus escapes from the LAA, it then can travel to other areas of the body, cut off blood supply, and cause a stroke (Cleveland Clinic, n.d.). AF can be persistent, paroxysmal, or permanent. Persistent AF lasts longer than 1 week. The arrhythmia may stop on its own or require medical therapy. Paroxysmal/intermittent AF is spontaneously and terminates in less than 7 days. Permanent AF continues and cannot be corrected. AF may be symptomatic, but is often asymptomatic. Up to one-third of all individuals with AF may not be aware of their condition (Steinhubl, Waalen, Edwards, Mehta et al., 2017). Symptomatic AF is often described as palpitations, syncope, chest discomfort, fatigue, and shortness of breath. Symptomatic AF is favorable because it can be detected and treated more efficiently. Asymptomatic AF is usually identified after having an embolic event, positive random ECG, or HF exacerbation; therefore, the disease is challenging to diagnosis and treat. The correlation



between symptoms and AF is unreliable for disease recognition. Patients with AF typically have other cardiovascular comorbidities (e.g., HF, obstructive sleep apnea [OSA]). These patients are at elevated risk of cardiovascular and thromboembolic events and mortality when compared with non-AF patients (Benjamin et al., 1998). Patients with AF are 5 times more likely to have a stroke than those who do not have AF (National Stroke Association. n.d.). The purpose of researching ICM and AF detection is to identify patients with AF earlier, increase treatment rates per guidelines, and increase knowledge by having constant electrocardiogram (ECG) capability. A study by Ziegler, Koehler, and Mehra (2006) demonstrated that extending the monitoring duration from 24 hours to 7 days significantly increased the AF detection rate. Additionally, according to Brignole et al. (2004), subcutaneous implantable monitors were largely accepted in clinical practice for diagnosing patients with unexplained syncope. Providers have a wealth of mechanisms when selecting a monitoring technique. The options vary from 48-hour Holter monitors, 3- to 7-day telemetry monitors, watches, 7-day patches, and implantable devices. The time needed to detect AF is still unknown; however, a recent CRYSTAL AF study reported 84-126 days was needed on average (Sanna et al., 2014). Providers are utilizing a haphazard approach in monitoring patients; therefore, are unable to identify an AF diagnosis. The ICM could potentially help guide individual patient treatment (Lim, & Lip, 2008).

Asymptomatic AF has major implications for society, can challenge national health care costs, and can require extra services post disease state. The current mainstay in treatment for AF is anticoagulation, but other treatment modalities offer promising results, including intervention approaches (e.g., Watchman device, left atrium clip). Diagnosis at older ages and/or with increased morbidity burden U.S. health care costs. For AF-verses-control subjects, the mean annual inpatient cost-per-patient were \$7,841 verses \$2,622, outpatient medical costs were

\$9,225 versus \$5,629, and outpatient pharmacy costs were \$3,605 versus \$3,714 (Benjamin et al., 1998). The total incremental costs for AF were \$8,705 per patient; the national incremental costs for AF were \$26 billion (Benjamin et al., 1998).

HF is a devastating outcome of AF; a chronic disease that must be managed with strict diet and daily medications. HF develops in as many as 40% of patients with AF (Schnabel et al. 2013; Wang et al., 2003). Among patients aged between 55-74 years, the 10-year mortality was 61.5% in men with AF compared to 30% in men without AF. Among women in similar age group, the 10-year mortality was 57.6%, in the AF group versus 20.9% in women without AF (Stewart, Hart, Hale, & McMurray, 2002). HF affects approximately 4.8 million people in the United States and Americans are spending over \$17 billion annually on treatments for HF (American Heart Association, n.d.). Patients are often readmitted to the hospital for HF exacerbation due to the difficulty in managing this disease.

Treatment for AF typically includes rate control, rhythm control, and embolic stroke risk protection with OAC. In patients with AF, 85%-90% may be candidates for OAC therapy (Freeman et al., 2015). Treatment for AF begins with risk stratification of the embolic probability and calculated risk stratification score; an anticoagulant is prescribed depending on the guidelines. Risk stratification involves assessing every patient for key elements, such as Congestive heart failure, Hypertension, Age, Diabetes, history of TIA or Stroke, Vascular disease, Age (again), and female Sex (CHA<sub>2</sub>DS<sub>2</sub>-VASC). Each element contributes 1 or 2 points; a total score of 2 or greater indicates that the patient should be prescribed an OAC. The higher the CHA<sub>2</sub>DS<sub>2</sub>-VASC risk score, the higher the embolic risk. Often patients do well on OAC (e.g., Xarelto, Eliquis, coumadin); however, patients must understand the bleeding risks versus the embolic risk when taking OACs. The bleeding risk often creates a dilemma with clinician

prescribing habits; the need to evaluate the risk of bleeding versus possible legal action. In the United States, multiple lawsuits have been filed alleging harm from blood thinners.

### **Research Aims**

This research study examined data using the following study aims:

AIM 1: Describe the patient demographics (e.g., age, gender, ethnicity, AF) of patients receiving care in an outpatient cardiology clinic.

AIM 2: Describe the relationship between the dependent variable (AF) and independent variables (e.g., BMI) in patients receiving care in an outpatient cardiology clinic.

AIM 3: Examine the frequency of AF diagnosis and the length of time to diagnosis in patients implanted with an ICM receiving care in an outpatient cardiology clinic.

AIM 4: Examine provider patterns of treatment with OACs.

AIM 5: Investigate documented considerations to diagnose or rule out OSA in a group of outpatient AF patients in a cardiology clinic.

## **Chapter 2**

### **Review of the Literature**

The purpose of this chapter is to summarize the current literature about AF with comprehensive literature search using Cumulative Index to Nursing Allied Health Literature (CINAHL), Google Scholar, Ovid SP, PubMed, Cochrane database and evidence-based medical reviews and current literature in nationally recognized journals. Key search terms were AF, cardiac monitors, cardioembolic events, and related terms. Additional articles from the reference sections were used from cited articles. AF is largely undiagnosed and can cause major morbidity and mortality. AF is the most common cause for stroke (Aguilar & Hart, 2008). Of those patients with AF, their average yearly risk for stroke is 5%, and the risk is increased in the presence of certain risk factors, including left ventricular dysfunction, hypertension, increasing age, and history of stroke (Atrial fibrillation Investigators 1994) and now has increased with the addition of risk factors such as diabetes, gender, CAD, renal impairment, sleep apnea or chronic obstructive pulmonary disease and vascular history. These are independent risk factors associated with increased stroke risk. (Mozaffarian, Benjamin, GO et al...) AF is the most prevalent sustained arrhythmia encountered in the emergency department (ED) and outpatient clinic and is frequently detected in those without a prior diagnosis of AF (Coll-Vinent, Martin, Malagon, & HERMES-F Investigators, 2015).

As the population ages, the risk for stroke increases (Mozaffarian et al., 2016). The population is living longer therefore the age that providers see to treat becomes older and treatment is longer. That is nearly 3 to 6 million people in the United States (Go et al., 2001).

All relevant guidelines suggest patients that are intermediate to high risk for stroke should receive OAC (Stiell, & Macle, 2010). Anticoagulation with warfarin was once the only

choice but now there are novel oral anticoagulants that provide better cover and less interactions for patients. When prescribing oral anticoagulants, the clinician balances the risk for bleeding and the risk for stroke in each patient individually. Based on those risk the clinicians can pick from the variety of anticoagulants based on compliance, bleeding risk, availability and cost among other preferences. Warfarin is often affected by the foods eaten or other medications prescribed or over the counter. International ratio blood work is also needed regularly to monitor therapeutic levels while on warfarin. With the new novel oral anticoagulants, patients are not restricted to a particular diet and do not have to monitor blood work while taking the OACS. Although anticoagulation is the goal in stroke prevention, often anticoagulation is not prescribed and if it is prescribed, the patients stopped taking the medication at 50% after 2 years (PINNACLE Registry Aug 2016). Currently, anticoagulation is prescribed in less than 55% of eligible patients (Lane & Lip, 2012). Forty percent of patients that were intermediate to high risk for stroke were under treated by receiving aspirin only (PINNACLE Registry Aug 2016). AF accounts for nearly 1 in 7 strokes (Roldán et al. 2013) and affects about 5.8 million people in the United States (Colilla et al., 2012). Therefore, the diagnosis is hard to identify and then, if the patient is diagnosed, appropriate treatment occurs less than 50% of the time. Documentation is key to supporting an accurate diagnosis. AF results in a five times greater risk of stroke and approximately 15% of strokes are due to AF (Wolf Abbott, & Kannel, 1991). ICMs play a substantial role as a safety net for the management of AF. Identifying AF is critical for guiding preventative therapy decisions. We now have ICMs that can continuously monitor patients for several years and detect episodes of asymptomatic AF that are as brief as a few seconds. (Sanna, Diener, Passman et al 2014). These monitors could assist in early diagnosis and identification of with followed treatment.

The Cryptogenic Stroke and Underlying Atrial Fibrillation study (CRYSTAL AF) assessed whether long term monitoring with an ICM was superior to standard monitoring for the detection of AF in patients with cryptogenic stroke at 6 months and 12 months. This study also looked at providers actions post diagnosis of AF. AF is defined as an irregular heart rhythm for more than 30 seconds without detectable p waves. The researchers found 6.4 times more patients to have AF over 6 months using ICM. They also noted the median time to AF detection was 84 days. After the diagnosis of AF, the majority (97%) who had AF were prescribed OACs. In support of longer monitoring, the REVEAL AF was a prospective study of previously undiagnosed AF as documented by an ICM in high-risk patients (Reiffel et al. 2017). AF is often silent and considered subclinical, therefore goes undetected until major morbidity and mortality occurs. Recent studies showed AF and symptoms that only 13% to 21 % of episodes with symptoms suggestive of AF reported by patients with implanted pacemakers were AF episodes according to the pacemaker log. (Quirino et al., 2009).

Use of intracardiac monitoring provides the clinician with daily ECGs for evaluation of arrhythmias for longer periods of time. Research on their use in the outpatient clinic setting is more limited. In a recent abstract present at American College of cardiology, even the ECG patch found 9 times more AF than conventional means of monitoring. They stated that the ECG patch had 5.1% rate of new AF diagnoses compared the usual controls at 0.6%. These researchers defined high risk patients as those 75 years or older, or at least 55 years old and male or 65 years old and female. Those younger than 75 years old had to have a least one risk factor such as prior cerebral vascular event, heart failure, hypertension plus diabetes, or OSA. (Steinhubl, 2018).

Risk factors such as congestive heart failure, hypertension, age, diabetes, history of TIA or stroke, vascular disease, and female gender have been identified and studied to increase embolic risk in patients with AF. OSA is a popular topic in current literature as another possible, pertinent risk factor for patients with AF that increases embolic risk. OSA is defined as a sleep disorder characterized by partial or complete obstruction of the airway due to the collapse of pharyngeal muscles, leading to the reduction of airflow (hypopnea) or complete absence of airflow (apnea; Mannarino, Di Filippo, and Pirro, 2012). Sleep apnea is diagnosed when a patient experiences five or more episodes of hypopnea or apnea per hour during sleep along with associated symptoms, such as daytime sleepiness (Mannarino et al., 2012). OSA has been linked to increase mortality and morbidity and associated with cardiac arrhythmias, heart failure, and stroke (Butt, Dwivedi, Khair, and Lip, 2010).

The STOP-BANG questionnaire is a valid and reliable tool to determine patients who are at risk for sleep apnea. The questionnaire uses subjective and objective data points to calculate a risk score. The screening tool assesses for snoring, tired, observed, body mass index  $>35\text{kg/m}^2$ , age  $>50$  years old, neck circumference  $>16$  inches (41 cm), and male gender. Scores are calculated as *low risk* (yes to 0-2 questions), *intermediate risk* (yes to 3-4 questions) and *high risk* (yes to 5-8 questions, or yes to 2 or more of 4 STOP questions and male gender, or yes to 2 or more of 4 STOP questions and BMI  $> 35 \text{ kg/m}^2$ , or **yes to 2 or more of 4 STOP questions and neck circumference  $\geq 17$  inches [43 cm] in males or 16 inches [41 cm] in females**). A research AIM in this study examines patients who have OSA; these patients also have up to four times the risk of developing AF when compared to patients without OSA (Anter et al., 2017). This study will test an innovative approach through the

use of ICM to assure that newly-diagnosed AF patients in an outpatient clinic are diagnosed early and risk-stratified with a therapeutic plan for OAC, if applicable. A cardiologist and cardiology nurse practitioner will use ICM data to improve the diagnosis of AF patients with prescribed stroke prophylaxis. Intracardiac monitoring is a novel and an innovative approach to providing a safety net for AF patients diagnosed in the outpatient clinic.



## **Chapter 3**

### **Methods**

The purpose of this research will add to the information on detecting AF earlier and assist in decreasing major morbidity and mortality by identifying AF earlier and treating with oral anticoagulants or procedures/treatments using ICMs to identify arrhythmias. This research will also investigate considerations for OSA in patients with AF.

#### **Study Design**

A retrospective database from an outpatient clinic in southern California was analyzed in this non-experimental study design; it comprised routinely-collected data on patients with an ICM implanted between June 3, 2014 and December 27, 2018. This study was designed to establish the incidence of AF using an ICM device (i.e., Medtronic LINQ) in the outpatient setting. To protect human subjects, Institutional Review Board approval was obtained from the University of San Diego. Study limitations were also addressed. All patients who received ICM devices from June 2014 through December 2018 in one outpatient cardiology clinic comprised this study population. The non-experimental design was appropriate for this study to assess relationships among variables. Patients initial demographics, diagnosis of AF, number of days from implant to AF event, implant justification, intervention with OACs, and assessment of sleep apnea risk were recorded and analyzed. Once the diagnosis of AF was determined, a cardiology nurse practitioner calculated embolic and bleeding-risk assessment scores for each patient.

In accordance with the 2014 ACC/AHA/ESC AF practice guidelines concerning patients with AF, the CHA<sub>2</sub>DS<sub>2</sub>-VASc score has been recommended to assess for stroke risk (January et al. 2014). The CHA<sub>2</sub>DS<sub>2</sub>-VASc (i.e., Congestive heart failure history, Hypertension history, Age > 75, Diabetes mellitus history, previous Stroke or TIA symptoms, Age 65-74, Vascular disease

history, and [female] Sex) is a risk-stratification tool that offers a comprehensive measurement (percentage) of a patient's risk for an embolic event over the next year (Lip et al. 2010). This tool is commonly used to determine guideline-based usage and prescriptions of OACs. The HAS-BLED (i.e., Hypertension, Abnormal renal/liver function, Stroke, Bleeding history or predisposition, Labile INR, Elderly, Drugs/alcohol) is another score that is recommended by the European and Canadian AF guidelines to estimate the risk for bleeding in anticoagulated and standard patients over the next year (Roldán et al. 2013). If the risk score utilizing the CHA<sub>2</sub>DS<sub>2</sub>-VASc is greater than 2 or the HAS-BLED score is less than 3, the patient is deemed appropriate for a prescribed OAC after risk and benefits have been discussed with the patient. Over estimation of bleeding risk is a significant barrier in prescribing OAC, especially among elderly patients (Lane & Lip 2013). Elderly patients are often thought to be at a higher risk of bleeding as well as a fall risk. To the contrary, these patients tend to be undertreated and are often times at a higher embolic risk due to increased age. These risk management scores enabled the clinician to assess the most appropriate antithrombotic therapy for stroke prophylaxis in non-valvular AF.

### **Sampling Procedures/Setting**

The study population included all patients in one southern California, outpatient cardiology clinic who had been implanted with the Medtronic LINQ. Patients without a history of AF but experiencing symptoms of palpitations, syncope, cryptogenic stroke, or suspected AF were enrolled.

### **Measures**

Data were collected on patients with CHA<sub>2</sub>DS<sub>2</sub>-VASc scores of ranging from 0 to 10 with two risk factors (e.g., CAD, renal impairment, sleep apnea). Data were accessed and

obtained from the patient's electronic medical records and the Medtronic LINQ Carelink database utilizing a standardized data collection form. This data form was then transferred into a password-protected Excel file for validation, auditing, and summarization. The assessment tools, CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED, have been statistically validated in research studies. CHA<sub>2</sub>DS<sub>2</sub>VASc has a pooled C statistic of 0.667 (95% CI [0.651, 0.683]) for patients taking anticoagulation therapy and 0.675 (95% CI [0.656, 0.694]) for non-anticoagulation patients (Chen et al. 2013). HAS-BLED demonstrated accuracy at predicting the risk of major bleeding (C statistic, 0.69, 95% CI [0.67, 0.72; Roldán et al., 2013). Categorical variables such as the presence of hypertension, diabetes, congestive heart failure, and vascular disease were compared using chi-square. Continuous or interval variables (e.g., age) were compared and correlated.

### **Specific Aims**

This study examined the following study aims:

AIM 1: Describe the patient demographics (e.g., age, gender, ethnicity, AF) of patients receiving care in an outpatient cardiology clinic.

AIM 2: Describe the relationship between the dependent variable (AF) and independent variables (e.g., BMI) in patients receiving care in an outpatient cardiology clinic.

AIM 3: Examine the frequency of AF diagnosis and the length of time to diagnosis in patients implanted with an ICM receiving care in an outpatient cardiology clinic.

AIM 4: Examine provider patterns of treatment with OACs.

AIM 5: Investigate documented considerations to diagnose or rule out OSA in a group of outpatient AF patients in a cardiology clinic.

**Data collection plan.** Once IRB approval was achieved, the data were de-identified to be compliant with Health Insurance Portability and Accountability Act (HIPPA) regulations.

The database was password protected and documentation, including the codebook, was locked in a drawer in the researcher's office. All data will be destroyed 10 years after data collection.

Patients with suspected AF with ICM between June 2014 and December 2018 were included in this convenience sample. At the time of this study, AF lasting 5 minutes or longer was associated with a significantly-increased risk for stroke or systemic embolism in patients with a pacemaker (Healey, Connolly, Gold et al. 2012); therefore, AF episodes longer than 6 minutes was used to determine an episode. After the patient was diagnosed with AF, the cardiologist or cardiology NP used the instruments to stratify the risk for stroke and bleeding. If the CHA<sub>2</sub>DS<sub>2</sub>-VASc score was greater than or equal to 2 and the HAS-BLED score was less than 3, the patient was educated on embolic and bleeding risk and joint decision was made to start an OAC or continue current treatment. Routine education was given to the patient at that time discussing the risks for stroke and bleeding as a standard procedure.

### **Data Analysis**

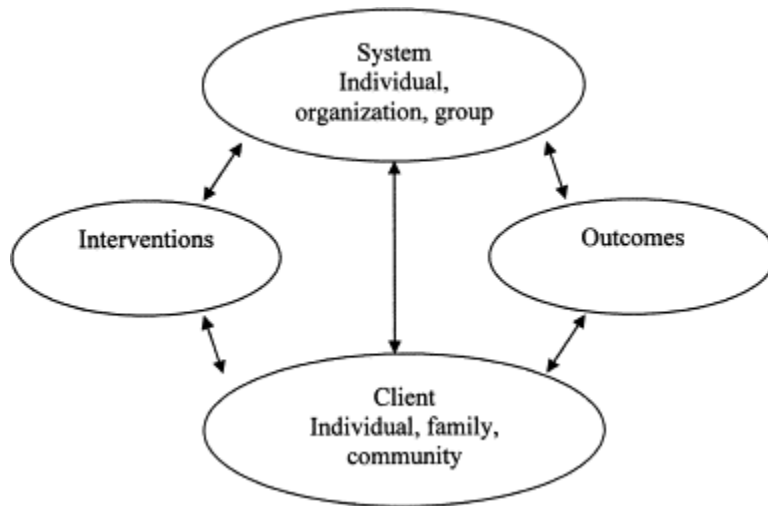
Statistical analysis was conducted using Microsoft Excel© and SPSS (Version 24). A power analysis using G\*Power (Faul, 2014) suggested that the minimum number of patients needed for the study was 200 with a moderate effect size .20 and an alpha of .05 for a two-tailed test. Descriptive statistics were used for demographics information with means, standard deviations, medians, skewness, and kurtosis, where appropriate. Pearson r and Spearman rho correlations were used to examine the relationships between ordinal and interval data. Chi square was used to test the frequencies between categorical variables. Study outcomes were compared with the incidence of AF in patients and previous symptoms, such as palpitations, syncope, and cryptogenic stroke. Secondary outcomes included the provider's response to AF and in combination with the CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED scores.

## Study Timeline

Three months were required for IRB approval. Subsequently, the collection of data was done over 6 months.

## Theoretical Model

The Quality Health Outcomes Model is the conceptual framework guiding this study (Figure 1). This model helps evaluate and compare the quality that a system places on their subjects (Mitchell, Ferketich, & Jennings, 1998). The model evaluates quality improvement and outcomes management through interventions within the system and the client (Mitchell et al). Through the Quality Health Outcomes Model, the study's conceptual framework works with the independent variables of patient demographics and the ICM. The dependent variables are the prescription of Nursing Implications



*Figure 1.* Quality health outcomes model. Adapted from “Quality health outcomes model. American Academy of Nursing Expert Panel on Quality Health Care,” by P. H. Mitchell, S. Ferketich, & B. M. Jennings, 1998, *Image: The Journal of Nursing Scholarship*, 30(1), p. 44.

## Chapter 4

### Results

The purpose of the study was to (a) describe patient demographics, (b) identify the percentage of patients identified with a diagnosis of AF, and (c) identify the length of time in days to diagnosis once an ICM was implanted into a cardiac patient. Additionally, this study examined (d) whether there is an increase in frequency in OACs prescriptions with detection of AF, and (e) whether there was an increase in frequency for OSA in patients with AF.

Inclusion criteria required that patients be adults aged 18 years or older, implanted with an ICM, and a primary diagnosis among the following: AF management, cryptogenic stroke, palpitations, suspected AF, syncope, or unknown reasons. Exclusion criteria eliminated those patients who were already on anticoagulation for therapy for an indication other than AF and those who were hemodynamically unstable. Patients diagnosed with valvular AF and patients already enrolled in a clinical trial were also excluded. Furthermore, patients whose primary language at home was other than English or Spanish were also excluded.

A portrayal of the sample population will be provided (Aim 1) along with descriptive statistics for the dependent and independent variables. Findings for Aim 2-to-Aim 6 will follow. Incidental findings will also be presented as possible future research.

#### Characteristics of the Sample

**Aim 1.** *Describe the demographic information (e.g., age, gender, ethnicity, AF) for patients receiving care in an outpatient cardiology clinic.*

A total of 269 patients implanted with an ICM comprised the subjects of this research study. A description of patients by gender and ethnicity are included in Table 1. Data about race was not incorporated into the patient charts and, therefore, could not be extracted.

Table 1

*Patient Information by Gender and Ethnicity*

	<i>N</i>	%
Gender		
Male	116	43.1%
Female	153	56.9%
Ethnicity		
Hispanic	57	21.2%
Not Hispanic	40	14.9%
Undetermined	172	63.9%

Participants in the study ranged from age 19-years to 93-years. The average age was normally distributed (Skewness = -0.630; Kurtosis = 0.349). Height (Skewness = -0.721; Kurtosis = 0.361) was also normally distributed but weight (Skewness = 0.966; Kurtosis = 1.108) was slightly leptokurtic and BMI was both positively skewed and leptokurtic (Skewness = 1.018; Kurtosis = 1.308). Table 2 provides descriptive detail about characteristics of these continuous variables.

Table 2

*Patient Characteristics (with Normal Distribution)*

	<i>N</i>	<i>M</i>	<i>SD</i>
Height (inches)	212	64.90	4.092
Weight (lbs)	210	176.93	47.718
BMI	207	29.17	6.143
Age (years)	255	65.24	15.056

After demographic information was extracted, patient records were examined to reveal the documented justification for patients receiving an ICM. Table 3 categorizes these underlying conditions.

Table 3

*Justification for Implant (N = 269)*

	<i>N</i>	%
AF Management	16	5.9%
Cryptogenic Stroke	53	19.7%
Palpitations	44	16.4%
Suspected AF	38	14.1%
Syncope	89	33.1%
Unknown	29	10.7

The number of days from implant-to-AF detection (Skewness = 1.018; Kurtosis = 1.308) was not normally distributed (i.e., slight, positive skew; leptokurtic). While the LINQ battery-life was limited to 3 years (1,096 days), one subject was an outlier and AF was detected over 3 ½



years after implant (1,289 days). Descriptive information about CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED scores, both ordinal scales, is also included on Table 4.

Table 4

*Non-parametric Patient Measures*

	<i>N</i>	Range	Median	Mode
Days to detection	63	2, 1289	154	10, 14
CHA <sub>2</sub> DS <sub>2</sub> -VASc	218	0, 8	4	4
HAS-BLED	218	0, 5	3	3

**Comparisons of Independent Variables to AF**

**Aim 2.** *Describe the relationship between the dependent variable (AF) and independent variables (e.g., BMI) in patients receiving care in an outpatient cardiology clinic.*

The second aim was to distinguish any differences in demographic information or diagnostic testing for those subjects whose ICM detected AF. Significant differences were found in age ( $M_{No} = 63.18$ ,  $M_{Yes} = 71.76$ ), CHA<sub>2</sub>DS<sub>2</sub>-VASc scores ( $M_{No} = 3.73$ ,  $M_{Yes} = 4.33$ ), and HAS-BLED scores ( $M_{No} = 2.56$ ,  $M_{Yes} = 3.04$ ). Height, weight, BMI, and Sleep Apnea Risk values were not significantly different between the two groups. See Table 5 for detailed information.

Table 5

*Significant Differences between Demographic/Diagnostic Information and AF Detection*

Variable	Detect AF	<i>N</i>	<i>M</i>	<i>t</i>	<i>p</i>
Age	No	194	63.18	3.995***	<.001
	Yes	61	71.76		
CHA <sub>2</sub> DS <sub>2</sub> -VASc	No	166	3.73	2.178*	.03
	Yes	52	4.33		
HAS-BLED	No	166	2.56	2.593**	.01
	Yes	52	3.04		

Note. \*  $p < .05$ ; \*\*  $p < .01$ ; \*\*\*  $p < .001$ .

Next, for subjects whose ICM identified AF, an ANOVA was performed to see if the reason for implant differed among the continuous demographic and diagnostic variables. For age and reason for ICM, patients with palpitations ( $M = 56.9$  years) were significantly younger than patients with suspected AF ( $M = 69.33$  years).

The number of days reported to detect AF was significant by reason for the implant in the overall model; however, a Scheffé post-hoc test failed to identify any specific variable difference (range from 57.75 days for AF management to 387.53 days for syncope). Table 6 summarizes these results.

Table 6

*Differences in Demographics by Reason for Implant*

	<i>df</i>	<i>F</i>	<i>p</i>
BMI	4, 184	1.123	.347
Age	4, 226	3.929**	.004
Detect Days	4, 58	3.287*	.017

Note. \*  $p < .05$ ; \*\*  $p < .01$ ; \*\*\*  $p < .001$ .

For other demographic variables, there was no difference in detection days between genders (males 25/116, females 38/153). While there were no differences between ethnicities or

BMI and detection days, patients with suspected AF had a significantly higher frequency of AF detected by the ICM ( $\chi^2 = 25.920, p < .001$ ).

**Assessing Time Needed to Diagnose AF**

**Aim 3.** *Examine the frequency of AF diagnosis and the length of time to diagnosis in patients implanted with an ICM receiving care in an outpatient cardiology clinic.*

The third aim examined the length of time (days) to diagnosis. Detection of AF occurred in 63 of the 269 subjects (23.4%) in this study. The days needed to detect were then compared to standard methods of monitoring patients to see the capture rate of AF detection. The median detection days was 154. Detection days ranged from 2 days to 1,289 days. Figure 2 displays these results.

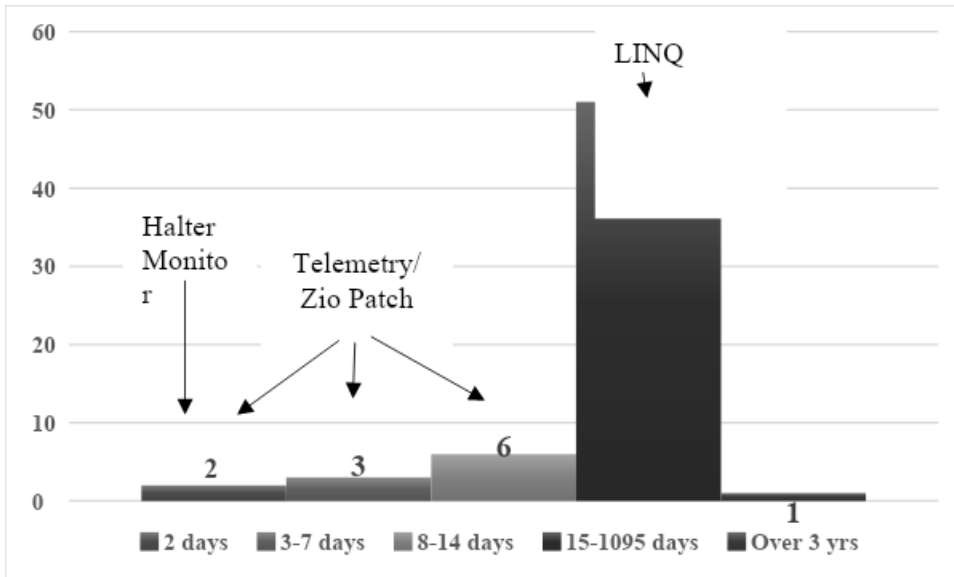


Figure 2. Number of days to detect AF with ICM compared with traditional monitors.

Other type of arrhythmias were also captured by the LINQ device. These rhythms are included in Table 7.

Table 7

*Arrhythmia Symptoms (N = 210)*

	<i>N</i>	%
Atrial Tachycardia (A Tach)	17	28.8
Ventricular Tachycardia (V Tach)	4	6.8
Supraventricular Tachycardia (SVT)	21	35.6
Premature Ventricular Contractions (PVC)	9	15.3
Bradycardia	8	13.6

**Treatment with Oral Anti-Coagulants (OACs)**

**Aim 4.** *Examine provider patterns of treatment with OACs.*

The fourth aim examined whether an increase in frequency occurred in patients prescribed OACs and detection of AF. Out of the 63 patients (23.4%) where AF was detected, 52.4% of those detected were on OACs (i.e., Eliquis, Xarelto). There was a significantly higher frequency of patients with detected AF on Eliquis and Xarelto ( $\chi^2 = 58.462, p < .001$ ). The average age of patients on Eliquis was 77-years and on Xarelto was 68 years. Descriptive information about Aim 4 can be found in Table 8.

Table 8

*Oral Anticoagulant Medications (N = 215)*

	<i>N</i> (All)	% All	<i>N</i> (Detected)	% (Detected)
Antiplatelet	34	12.6	4	6.3
Eliquis	20	7.4	15	23.8
Xarelto	33	12.3	18	28.6
None	128	47.6	15	23.8
Missing	54	20.1	9	14.3

When patients were risk-stratified, two scoring tools are used to determine embolic (stroke) risk. For the instrument, CHA<sub>2</sub>DS<sub>2</sub>-VASc scores range from 0 to 8. The median CHA<sub>2</sub>DS<sub>2</sub>-VASc score of the sample was 4. Likewise, the HAS-BLED scores range from 0 to 8 and this sample of patients had a median score of 3.

### **Obstructive Sleep Apnea (OSA) and AF**

**Aim 5.** *Investigate documented considerations to diagnose or rule out OSA in a group of outpatient AF patients in a cardiology clinic.*

The fifth aim was to determine whether there was an increased frequency of OSA for patients with AF. For this assessment of OSA risk, the STOP-BANG tool was used. Detailed results are presented in Table 9.

Table 9

*Questionnaire Responses for STOP-BANG*

	Yes (% of Total)	No (% of Total)	Missing (% of Total)	% of Yes to Known (Valid %)
Snore	65 (24.2)	36 (13.4)	168 (62.5)	64.4%
Fatigue	63 (23.4)	38 (14.1)	168 (62.5)	62.4%
Breath	33 (12.3)	68 (25.3)	168 (62.5)	32.7%
Hypertension	180 (66.9)	39 (14.5)	50 (18.6)	82.2%
BMI > 35 kg/m <sup>2</sup>	33 (12.3)	183 (68.0)	53 (19.7)	15.1%
Age > 50	193 (71.7)	29 (13.1)	47 (17.5)	86.9%
Neck > 17" (Male)	7	11	251	38.9%
> 16" (Female)	(2.6)	(4.1)	(93.4)	
	Male	Female		
Gender	116 (43.1)	153 (56.9)		

The total score of the STOP-BANG assessment is used to assess the risk categories of OSA. This instrument was administered through multiple attempts at telephone contact. A total of 99 patients could be reached to complete this 8-question survey. Simple scoring can establish *Low* and *Intermediate* risks but *High* risk identification follows an algorithm outlined on p. 11. Table 10 shows the distribution of subjects by risk category.

Table 10

*Assignment of Risk Score (N = 99)*

Risk Category (Score)	<i>N</i>	%
Low (0-2)	19	7.1%
Intermediate (3-4)	18	6.7%
High (see algorithm)	62	23.0%
Total	99	36.8%
Missing data	170	63.2%

To assess whether correlations existed between the STOP-BANG other data gathered in this study, Pearson *r* and Spearman rho calculations were performed based on the characteristics of each variable. There was a positive correlation between STOP-BANG sleep apnea scores and BMI ( $\rho = .425, p < .001$ ). This could suggest that the higher one's weight, the more likely that patient was at risk for OSA.

In addition, there was an inverse correlation between STOP-BANG sleep apnea scores and AF detect days ( $\rho = -.504, p > .01$ ). This suggests that, the higher the STOP-BANG score, the fewer days pass before AF detection with the ICM.

**Incidental Findings**

A positive correlation was identified between the CHA<sub>2</sub>DS<sub>2</sub>-VASc scores and HAS-BLED scores ( $r = .701, p < .001$ ). Specifically, as CHA<sub>2</sub>DS<sub>2</sub>-VASc scores increased, so did the HAS-BLED scores.

Several significant correlations were seen between age and other variables collected in this study. Age had a significant, moderate, positive correlation with the CHA<sub>2</sub>DS<sub>2</sub>-VASc scores ( $r = .523, p < .001$ ). Age was also moderately and positively correlated to the days needed to

detect AF ( $\rho = .449, p < .001$ ). Other significant and non-significant correlations are presented in

Table 11

Table 11

*Pearson r and Spearman rho (†) Correlations*

	CHA <sub>2</sub> DS <sub>2</sub> -VASc	HAS-BLED	Age	BMI†	Detect Days†
CHA <sub>2</sub> DS <sub>2</sub> -VASc	1				
HAS-BLED	.723***	1			
Age	.558***	.567***	1		
BMI†	-.255***	-.189**	-.405***	1	
Detect Days†	.255	.063	.449***	-.240	1
STOP-BANG	.071	.241*	-.029	.425***	-.504**

Note. † Spearman rho. \*  $p < .05$ ; \*\*  $p < .01$ ; \*\*\*  $p < .001$ .

Another incidental finding was uncovered among the limited number of OSA assessments. With documented OSA risk, information was extracted from the patient’s chart about their OSA diagnosis, referral, and follow-up (Table 12).

Table 12

*Patients At-Risk for Sleep Apnea*

	<i>N</i>	%
Diagnosed with sleep disorder	16	5.9
Sleep study ordered	2	0.7
Negative per sleep study	3	1.1
Unknown or Missing	248	92.3



## **Limitations**

Data were collected between the hours of 8:00 a.m. and 5:00 p.m., Monday thru Friday. Another limitation was that the data were collected in a single office; therefore, this study population might not be generalizable to other settings. Potential errors with medical records and data entry could have occurred with data input. Potential confounders were rapid cardiac rhythms that could have been misdiagnosed and medical conditions that might have developed prior to implant. Some patients failed with follow up by not connecting their monitors to the wall-unit transmitter or by not reconnecting or reprogramming the monitor when an error occurred. Other patients may have decided to or needed a change of cardiologists due to insurance or preference. Future studies should be designed to capture these potentially significant confounders.

## **Summary**

This chapter presented the results of the data analysis for this study. Each of the five research aims were outlined and interpreted. Incidental findings were also presented to possibly guide future studies. The limitations experienced in data collection were also addressed.

## **Chapter 5**

### **Conclusions**

#### **Discussion of Findings**

This research addressed five areas of inquiry examining the available data on 269 patients who received an ICM and the potential assessment of AF. The first aim of this retrospective study described the patient demographics. The second aim stratified groups (e.g., reason for implant) and compared them with the length of time needed to identify AF. The third aim analyzed the length of time in days to diagnosis. Aim 4 examined the frequency of OAC prescriptions with the detection of AF. The fifth aim scrutinized AF detection in patients who were also at risk or had been identified as having OSA. Finally, significant observations not incorporated into the five research aims were presented as evidence of the need for future research.

This chapter will discuss and summarize the research design, method, data analysis, and overall results. Nursing implications will also be addressed.

This study provided profuse amounts of scientific knowledge regarding patients who received an ICM in a southern California cardiology outpatient clinic comparing and contrasting those treated for AF and those not yet diagnosed. This retrospective database study design was performed in a setting that routinely-collected data on patients with ICMs implanted from June 1, 2014 through December 31, 2018. The sample had a similar distribution of age groups for males and females, but this population contained 37 more female patients. Information about race and ethnicity was not routinely captured in the existing database. A description of the average/median patient would be female, 5'5" in height, and 180 pounds in weight.

The incidence of AF using an ICM (i.e., Medtronic LINQ) device in an outpatient clinic was 23.4%, similar to national studies stating that longer monitoring of cardiac rhythms increased the diagnosis of arrhythmias. Only 12.7% of detected AF occurred before 14 days, the maximum amount of time available through the use of other, traditional monitors in standard use; therefore, a surprising 87.3% of detected arrhythmias found with the ICM could have remained unidentified. To recap, shorter monitoring devices have arrhythmia-detection capabilities up to 2 days (Holter monitor) or 7-14 days (Telemetry, Zio Patch), a disappointing statistic considering that the median number of days needed to detect AF in this study was 154 days ( $M = 270$  days). For monitors that had been implanted within the last 18 months, 30.17% detected AF. This equals the CRYSTAL AF study (Sanna et al., 2014); however, the CRYSTAL AF study only examined patients with cryptogenic stroke and suspected AF and the present study included multiple symptomology, including palpitations and syncope.

The ICM monitors are a useful way to identify arrhythmias without the patient being responsible for the maintenance and control the device. The automatic download by wireless function decreases data entry error.

Intracardiac monitors are also useful in assisting with stroke-risk stratification and bleeding risks among patients diagnosed with AF. Previously, AF patients at risk for stroke were prescribed warfarin; however, the potential benefit of OACs was found to significantly improve the composite of stroke or systemic embolic events by 19% when compared with warfarin (Hart, Pearce, & Aguilar, 2007). Presently, OACs are used more frequently, particularly after the PINNACLE trial (Hsu et al., 2016). In the PINNACLE Trial, less than 55% of patients who were considered at moderate-to-high risk for stroke received OACs; this study found that 63.5% of those patients were treated with OACs. This increase in treatment for this study may be due

in part to the new OACs. The number of patients who are not on OACs could be explained by the WATCHMAN procedure or fall risk, both contraindications for OAC use. These factors were not taken into account for not prescribing OACS in this patient population. During the PINNACLE trial, warfarin was the only option for anticoagulation. Newer anticoagulants have lower bleeding risk profiles; are easier to prescribe; simpler to manage, with no weekly blood draws; and do not interfere with foods or most other medications. This may provide some security in prescribing habits by clinicians. These factors were not taken into account for not prescribing OACS in this patient population.

### **Future Studies**

Future studies should examine links between OSA and the detection of AF. With an inadequate number of responders to the STOP-BANG instrument ( $n_{no} = 74$ ,  $n_{yes} = 25$ ), statistical significance could not be achieved in this study but the data were trending toward a higher score on the STOP-BANG score in those patients diagnosed with AF. As the STOP-BANG scores were normally distributed ( $M = 3.93$ , Median = 4, Mode = 4,  $SD = 1.599$ , Skewness =  $-0.188$ , Kurtosis =  $-0.214$ ), a comparison was made between patients diagnosed with AF and those who did not have documented AF. The comparison between these groups was not statistically significant, but warrants further examination (Figure 3).

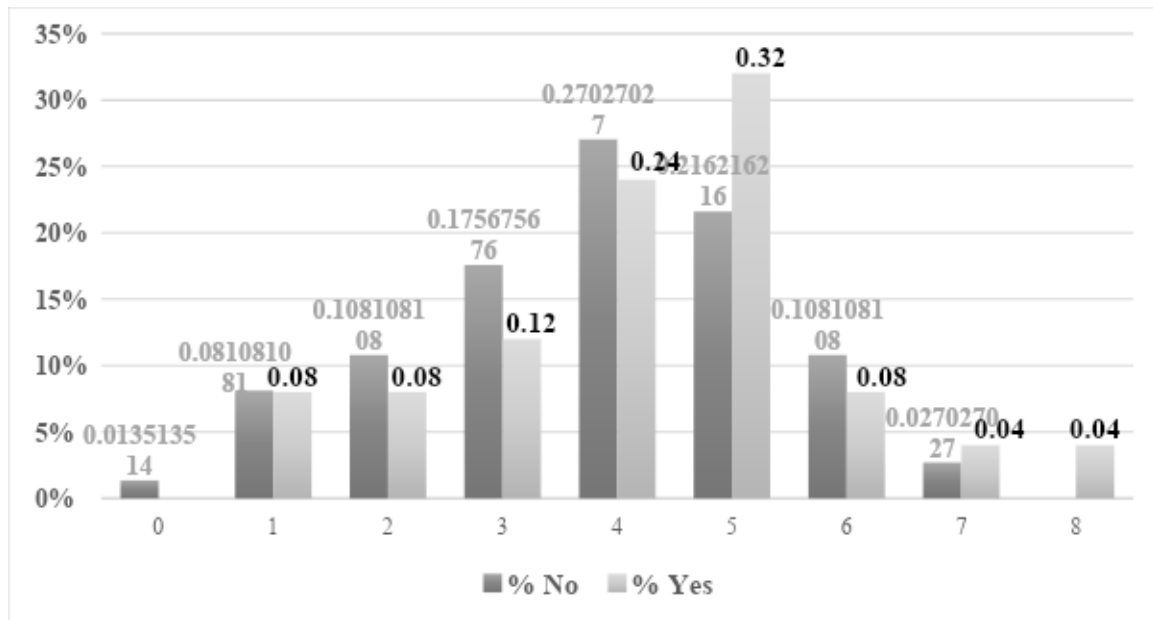


Figure 3. Comparison of STOP-BANG scores between AF and non-AF patients.

Future studies should examine OSA and AF detection in larger sample size and multiple locations. In this study, responses were captured by phoning each patient 1-to-3 times to answer a subjective questionnaire, STOP-BANG. As STOP-BANG scores increased, the number of days needed to detect AF was lower. Most patients in this research study were at moderately high risk for OSA (Median = 4). BMI was not significant in relation to AF, but presents another factor worthy of further examination.

### Implications for Nursing

This study reveals pivotal points for focused research with AF. With new, longer monitoring capabilities, the identification of disease and decrease in morbidity for AF patients is more promising. This research study aligns with larger studies performed (Hsu et al, 2016). Continued research with AF should be conducted to provide adequate information for the implementation of tailored intervention programs that encourage extended monitoring devices, encourage standardized protocols and guidelines for arrhythmias management, foster and educate policymakers, and address insurance loopholes that require shorter monitor devices. Prevention

of major comorbidities (e.g., thromboembolic events) are also important and possible with an increase in identifying AF. With an increase in the cost of rehabilitation and level of care needed for patients after these events, the benefit from identifying this cardiac arrhythmia sooner will save health care costs and improve quality of life. The adoption and utilization of health information technology is still relatively low among patients with chronic disease.

### **Conclusion**

As evidenced by this study, most patients would not have been identified with AF utilizing the shorter-duration monitoring devices typically used as the first line of treatment. Longer monitoring capabilities promise early identification of disease and reduction in morbidity for AF patients and will also increase awareness and aid in decision-making when seeing patients in the outpatient setting. The prevention of major comorbidities such as thromboembolic events are also possible with an increase in identifying AF. The cost-avoidance of rehabilitative care for AF sequela may be realized by identifying this cardiac arrhythmia sooner.

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## Appendix

### USD Institutional Review Board Approvals



Apr 16, 2018 4:14 PM PDT

Lisa Alvarez  
Hahn School of Nursing & Health Science

Re: Exempt - Initial - IRB-2018-375, Early Identification and Intervention in patients with Atrial Fibrillation using an Implantable Cardiac Monitor to Significantly Improve Guideline-Based Anticoagulation Therapy in an Outpatient Cardiology Clinic

Dear Lisa Alvarez:

The Institutional Review Board has rendered the decision below for IRB-2018-375, Early Identification and Intervention in patients with Atrial Fibrillation using an Implantable Cardiac Monitor to Significantly Improve Guideline-Based Anticoagulation Therapy in an Outpatient Cardiology Clinic.

Decision: Exempt

Selected Category: Category 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Findings: None

Research Notes:

Internal Notes:

*Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.*

*The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited or exempt review at any time.*



Sincerely,

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*Dr. Thomas R. Herrinton*  
*Administrator, Institutional Review Board*

*Office of the Vice President and Provost*  
*Hughes Administration Center, Room 214*

*5998 Alcalá Park, San Diego, CA 92110-2492*  
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Sep 27, 2018 8:20 AM PDT

Lisa Alvarez  
Hahn School of Nursing & Health Science

Re: Modification - IRB-2018-375 Early Identification and Intervention in patients with Atrial Fibrillation using an Implantable Cardiac Monitor to Significantly Improve Guideline-Based Anticoagulation Therapy in an Outpatient Cardiology Clinic

Dear Lisa Alvarez:

The Institutional Review Board has rendered the decision below for IRB-2018-375, Early Identification and Intervention in patients with Atrial Fibrillation using an Implantable Cardiac Monitor to Significantly Improve Guideline-Based Anticoagulation Therapy in an Outpatient Cardiology Clinic.

Decision: Exempt

Findings: None

Research Notes:

Internal Notes:

*Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.*

*The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited or exempt review at any time.*

Sincerely,

*Dr. Thomas R. Herrinton  
Administrator, Institutional Review Board*

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Apr 18, 2019 8:42 AM PDT

Lisa Alvarez  
Hahn School of Nursing & Health Science

Re: Renewal - IRB-2018-375 Early Identification and Intervention in patients with Atrial Fibrillation using an Implantable Cardiac Monitor to Significantly Improve Guideline-Based Anticoagulation Therapy in an Outpatient Cardiology Clinic

Dear Dr. Lisa Alvarez:

The Institutional Review Board has rendered the decision below for IRB-2018-375, Early Identification and Intervention in patients with Atrial Fibrillation using an Implantable Cardiac Monitor to Significantly Improve Guideline-Based Anticoagulation Therapy in an Outpatient Cardiology Clinic.

Decision: Exempt

Findings: None

Research Notes:

Internal Notes:

*Note: We send IRB correspondence regarding student research to the faculty advisor, who bears the ultimate responsibility for the conduct of the research. We request that the faculty advisor share this correspondence with the student researcher.*

*The next deadline for submitting project proposals to the Provost's Office for full review is N/A. You may submit a project proposal for expedited or exempt review at any time.*

*Sincerely,*

*Dr. Thomas R. Herrinton  
Administrator, Institutional Review Board*

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