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Novel Oral Anticoagulants: Bedrest and Bleeding in Patients Undergoing Atrial Fibrillation Catheter Ablation

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NOVEL ORAL ANTICOAGULANTS: BEDREST AND BLEEDING IN PATIENTS
UNDERGOING ATRIAL FIBRILLATION CATHETER ABLATION

by

Lynn McWhirter

A project submitted to the School of Nursing
in partial fulfillment of the requirements for the degree of

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Certificate of Approval

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Dedication & Acknowledgements

I would like to dedicate this to my parents, Henry and Doris McWhirter, whom taught me the value of education and made me believe that I could accomplish whatever I set out to do. I would like to acknowledge my family, friends, professional and academic colleagues in supporting me during my doctorate of nursing practice journey. My husband, Jimmy Neeson, could not have been more supportive of my efforts in this and my previous academic pursuits. He has seen me learn to turn on a computer to now completing this project. His extra support, understanding, love, and encouragement have been appreciated more than he will ever know. My sister, Gail McWhirter, was the impetus behind my enrollment. I began my doctoral studies when she was enrolled in her Mental Health NP program, and she has long since graduated and begun her practice. She never underestimates my abilities and is one of my biggest supporters. She has been a tremendous sounding board and editor along the way. My coworkers and friends, Melanie Blair, Michel Hartley, and Karin Prussak have been supportive, understanding, and collaborative during this process. My supervisor, Leslie Janik, has been enthusiastic, supportive, and helpful in completing this project and I am very grateful to her. Without the support of my supervising physicians, Dr. Fred Kusumoto and Dr. Kalpathi Venkatachalam, this project would not have been feasible. I will be forever grateful for their support of my efforts.

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Abstract

Atrial fibrillation (AF), the most common cardiac arrhythmia in persons over age 65, is associated with an increased stroke risk necessitating the need for long-term oral anticoagulation for risk reduction. With the introduction of direct thrombin and factor Xa inhibitors in the US since 2010, these novel oral anticoagulants (NOACs) are increasingly being prescribed, replacing the use of warfarin, a vitamin K antagonist. AF catheter ablation (CA), an elective procedure requiring femoral vascular access is a treatment for drug refractory and persistent AF. Bedrest, limb immobilization, and limited head of bed elevation are nursing measures utilized following femoral venous, and sometimes arterial, sheath removal and hemostasis. Limited research is available on the appropriate duration of bedrest to minimize bleeding complications associated with AF ablation in patients who use NOACs. The purpose of this quality improvement project was to compare and evaluate the effect of bedrest duration on post-procedure bleeding outcomes, urinary complaints, and back pain among patients taking NOACs while undergoing AFCA.

Thirty patients undergoing elective AFCA on NOACs were orally consented to participate in the study and placed on shortened (8 hours) or prolonged (>8 hours) bedrest following vascular hemostasis. Outcome measurements included bleeding after ambulation, back pain, and urinary complaints. Fifteen patients (50%) were on shortened bedrest and 15 (50%) were on prolonged bedrest. No statistically significant difference in bleeding, urinary complaints, or back pain were found. Since there is no clear advantage to prolonged bedrest for patients on NOACs after an AFCA procedure, clinicians should consider this when deciding on bedrest duration for their patients.

Chapter I: Introduction

Atrial fibrillation (AF), irregular rapid contractions of the atria asynchronously from ventricular contractions, is the most common cardiac arrhythmia. With an estimated prevalence of 3.4 million persons in 2010, 12 million people are predicted to have the problem by 2050 in the United States (US) alone (Centers for Disease Control [CDC], 2010; Lloyd-Jones et al., 2011; Naccarelli, Johnston, Dalal, Lin & Patel, 2012). One-third of hospitalizations are a result of cardiac arrhythmias, with a 66% reported increase in hospitalizations for AF over the past two decades. Advancing age, chronic cardiovascular disease, and more diagnoses through outpatient telemetry monitoring has been cited for the increase in numbers (CDC, 2010; Lloyd-Jones et al., 2011; Fuster et al., 2006). Treatment of AF represents a significant health care burden to both patients and healthcare providers. The estimated cost of the treatment of atrial fibrillation of US patients in 2005 was \$6.65 billion per year, including the costs of hospitalization, in- and outpatient health care, and medications (Coyne, Paramore, Granady, Mercader, Reynolds, & Zimetbaum, 2006). Hospitalization costs comprise up to 70% of costs spent on treatment of AF (Gorenek, & Kudaiberdieva, 2013). The estimated average cost in the US is \$3600 annually per patient. The incidence of atrial fibrillation increases with age. The median age for patients with atrial fibrillation is 66.8 years for men and 74.6 years for women (CDC, 2010).

The mortality rate from AF as either the primary or an underlying cause of death has been increasing for more than two decades. Thromboembolic (TE) cerebral events and congestive heart failure (HF) represent two of the most common and costly complications of AF, and are associated with increased mortality (CDC, 2010). Stroke risk is increased two to seven-fold in

persons with AF with an annual ischemic stroke risk of approximately five percent annually. AF may cause up to 15 to 20 % of ischemic strokes in the U.S. and increases one's risk by five times (CDC, 2010; Fang et al., 2008).

Thrombus formation in AF, attributed to low flow, or stasis of atrial blood, most often accumulated in the left atrial appendage, is associated with cerebral TEs in AF. Known atrial stunning and stasis occurs with cardioversion from AF to sinus rhythm (SR), whether spontaneous, chemical or electrical (Fuster et al, 2006). Progressive improvement of atrial stunning usually occurs with conversion over days to several weeks, and varies in intensity based on severity of heart disease and duration of AF. This thrombus accumulation propensity with AF is the cornerstone of the stroke risk and need management with antithrombotics.

Treatment of Atrial Fibrillation

Treatment of AF is predicated on symptom management, prevention of TE, and restoring a normal rhythm (Fuster et al., 2006). Standard treatment options of AF include rate control and rhythm control strategies including anti-arrhythmic drug therapy (AAD), and direct current cardioversion (DCC). Atrial fibrillation catheter ablation (AFCA) has emerged over the last decade as a viable rhythm control treatment option, usually as a second line treatment when failure has occurred and the individual is considered drug refractory AF (Calkins & Dewire, 2013).

Anticoagulation

Persons with diagnosed nonvalvular AF are administered oral anticoagulants (OAC) for thromboprophylaxis. Historically, OAC therapy has been limited to warfarin, a vitamin K antagonist (VKA) with many unfavorable qualities and limitations including food-food and food-drug interactions, a narrow therapeutic index, slow onset of action, a long half-life, major

bleeding, and the need for routine laboratory blood testing and monitoring of a patient's international normalized ratio (INR) blood level for dose titration. For these reasons, many patients have difficulty with maintaining a time in therapeutic range (TTR) and are at increased stroke risk in AF despite taking an OAC (Camm et al, 2012; Fuster et al., 2011; Maan et al., 2012). Since the Food and Drug Administration (FDA) approval of dabigatran etexilate, a direct thrombin inhibitor, the options for OAC have exploded, and the agents are termed novel oral anticoagulants (NOAC).

Dabigatran was the first new OAC available in more than 50 years. As of this writing, rivaroxaban and apixaban, oral direct Factor Xa inhibitors, have also received FDA approval in the U.S. for stroke prevention in nonvalvular AF. Like dabigatran, the Factor Xa inhibitor NOACs entered the marketplace following the release of several head-to-head trials of warfarin and the NOACs in which they were found to be more efficacious in stroke and systemic embolic prevention, carry a lower risk of intracranial bleeding, and have a favorable safety profile in AF patients (Miller, Grandi, Shimony, Filion, & Eisenberg, 2012). In 2012, the European Society of Cardiology (ESC) updated their 2010 guidelines for atrial fibrillation, concluding that NOACs

offer better efficacy, safety, and convenience compared to OAC with VKA's. Thus, where an OAC is recommended, one of the NOACs—either a direct thrombin inhibitor (dabigatran) or an oral factor Xa inhibitor (rivaroxaban, apixaban), should be considered instead of adjusted dose VKA (INR 2-3) for most patients with AF. (Camm et al., 2012, p. 2731)

There was no recommendation for one of the NOACs over another due to insufficient evidence.

With the advent of NOACs, patients and providers have alternative options. Because NOACs offer a more predictable pharmacokinetic profile than that of warfarin, there is no need for monitoring the INR level and adjusting the dose to achieve a target range, making this a more acceptable therapy. Evolutionary changes in stroke risk prophylaxis for AF with these NOACs offer patients many options to choose from based on personal preferences and risk profiles. The

NOACs do not have a safe and acceptable antidote, unlike warfarin. This elicits fear and uncertainty in the event of major bleeding. For these reasons, many practitioners and patients are slow and cautious when transitioning to their use. Ongoing safety and efficacy research will need to guide clinical practice. With many AF patients now taking NOACs, preventive and effective management of bleeding complications and inquiries are necessary of the providers to stay abreast of evolving issues related to NOAC use as it becomes available.

Pharmacologic therapy

Either a rate or rhythm control strategy is acceptable treatment of symptomatic AF, and has similar mortality outcomes (Wyse et al., 2002). Rate control is attained with beta-blockers, nondihydropyridine calcium channel antagonists, digitalis, alone or in combination with amiodarone. Rhythm control strategies for pharmacologic cardioversion or maintenance of sinus rhythm (SR) may include flecainide, dofetilide, propafenone, and ibutilide. Quinidine or procainamide administration may be considered but the usefulness is not well established. Digoxin and sotalol are not recommended for pharmacological cardioversion. Hospital admission and monitoring is required for initiation of quinidine, procainamide, disopyramide, and dofetilide for pharmacological cardioversion from AF to SR (Fuster et al., 2006).

Catheter ablation

Catheter-based atrial fibrillation ablation, which began in the late 1980's, is now one of the most performed ablation procedures in large US hospitals (Calkins & Dewire, 2013). The procedure is performed in the laboratory under anesthesia sedation. With ablation catheters and mapping systems, the goal of AFCA is eradication of AF through pulmonary vein isolation (PVI) using radiofrequency or cryoablation of the AF pathways. Vascular access is obtained via the femoral vein with adjuvant femoral artery monitoring in some cases. The femoral sheaths are

removed following the procedure in a recovery holding area when the physician and staff deem the patient hemodynamically stable with an acceptable activated clotting time. Achieving groin hemostasis is traditionally performed by manual compression and use of FemoStop compression devices. The patient is confined to bed for a specified time period with immobilization of the affected extremities for management of vascular access bleeding complications. Further patient activity restrictions include head of bed (HOB) limitations and use of indwelling urinary catheters in lieu of bathroom privileges.

AFCA risks include pericardial effusion, vascular access complications requiring surgery or blood transfusion, cardiac tamponade, hemothorax, stroke, sepsis, pneumonia, phrenic nerve injury and paralysis, esophageal injury, atrio-esophageal fistula, PV stenosis, radiation exposure, acute coronary artery occlusion, periesophageal vagal injury, mitral valve trauma, post procedural arrhythmias (Calkins et al., 2007). The rate of complications varies based on many factors with bleeding related complications the most common. Anticoagulation further compounds the bleeding issue, as it is necessary to prevent stroke. Bleeding complications may be compounded due to need for aggressive intraprocedural anticoagulation with intravenous (IV) unfractionated heparin to minimize catheter clotting and thromboembolic events. With additional use of NOACs, and their lack of a reliable antidote, bleeding complications are increasingly worrisome for patients and providers.

Overview of the Problem

Bleeding complications are long recognized and associated with femoral vascular access in percutaneous cardiac procedures including catheter ablation, coronary angiography, and percutaneous coronary interventions (PCI) (Merriweather & Suzbach-Hoke, 2012; Mohammady, Heidari, Sari, Zolfaghari, & Janani, 2013; Prudente et al., 2009; Raviele et al., 2012). Bedrest,

compression, and lower extremity immobilization are commonly used nursing management tools to maintain femoral access hemostasis and minimize complications of bleeding. Femoral vascular access bleeding complications will manifest as bruising, hematoma, pseudoaneurysm, and arteriovenous fistula. More serious and life threatening complications of cardiac tamponade and hemothorax may also occur rarely. Complications can lead to longer hospitalizations, surgical procedures, and increased costs (Raviele et al, 2012, Shoulders-Odom, 2006).

Early ambulation of patients post-cardiac catheterization and PCI is widely recognized to be associated with fewer adverse outcomes which may include deep vein thrombosis, back pain, difficulties with eating, drinking, and voiding, and overall patient dissatisfaction (Schiks et al., 2008). Post-PCI or AFCA bedrest may vary from 4 to 18 hours after femoral access sheath removal, with patients taking anticoagulants. Both groups of patients undergo anticoagulation in conjunction with their respective cardiac procedures and are cared for by the same nursing staff. No consistency or evidence exists on the optimal time to minimize bleeding risk and decrease adverse outcomes of prolonged bedrest. Very limited, to no research, is available on post-operative bedrest recommendations to mitigate bleeding complications in the post-AFCA patient population on NOACs.

Purpose of Project

The project purpose was to evaluate primary and secondary outcomes based on the duration of bedrest in patients undergoing AFCA on NOACs. Primary outcome measurements will include bleeding complications: bruising, hematoma formation, pseudoaneurysm and arteriovenous fistula formation. Secondary outcomes will include urinary complaints including need for catheterization, hematuria, frequency, urgency, and back pain while on bedrest. The goal of this project was to explore bedrest duration effects in order to minimize the patient

discomfort of prolonged bedrest and urinary catheters, standardize the postoperative care of AFCA patients on NOACs, while maintaining safe practice through implementation of a standardized post-procedural protocol for bedrest and activity restrictions in patients on NOACs.

Definitions

Atrial fibrillation

For the purposes of this project, AF was defined as paroxysmal or persistent in character as classified in ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation (Fuster et al., 2006).

Anticoagulation

For the purposes of this project, anticoagulation refers to both oral and IV antithrombotics, but did not include antiplatelet medications such as clopidogrel or aspirin.

Bleeding Complication

A bleeding complication was measured as bleeding requiring reapplication of manual pressure and/or pressure dressing or device, a hematoma larger than 5 centimeter (cm) in width, or blood loss requiring transfusion, additional bedrest, additional testing, or increased length of hospital stay.

Shortened Bedrest

For the purposes of this project, shortened bedrest was eight hours or less.

Prolonged Bedrest

For the purposes of this project, prolonged bedrest was greater than eight hours.

Urinary Discomfort

For purposes of this project, urinary discomfort was defined as difficulty with urination requiring reinsertion of catheterization, patient reported burning or bleeding with urination.

Back Pain

For purposes of this project, back pain was assessed by nursing with the widely used 1 to 10 point pain scale, and will be classified as mild (0-3), moderate (4-6), or severe (7-10).

Summary

Atrial fibrillation and management with CA is growing exponentially as patients seek curative treatment of the highly prevalent condition. With the attractiveness and favorable outcomes of NOACs for ease of use in stroke risk reduction, evidence based care of these patients is necessary for optimal outcomes. AFCA, like percutaneous transfemoral coronary interventions, requires femoral vascular access and sheath removal, maintenance of hemostasis, and management of bleeding complications. While research abounds on optimal time for bedrest and early ambulation in the cardiac catheterization and PCI patient population, very little is available on the newer AFCA patient needs. This project will evaluate the bleeding outcomes of varying post-procedural bed rest times in AFCA patients taking NOACs, in hopes of adding to the limited body of knowledge currently available in this arena.

Chapter 2: Literature Review

A brief overview of the bedrest literature is followed by a description of the search strategies and criteria employed to determine the use of bedrest and immobilization in prevention of bleeding complications following femoral vascular access in cardiac procedures. This is followed by a synthesis of the evidence and implications for the direction of the project.

Bedrest Following Procedures Requiring Femoral Vascular Access

Although bedrest and affected lower limb immobilization is the accepted practice following invasive femoral artery and vein access procedures following sheath removal and hemostasis, prolonged bedrest and immobilization have been cited with increased patient dissatisfaction, back pain, and difficulty with urination with resultant urinary catheterizations (Merriweather & Suzbach-Hoke, 2012; Shoulders-Odom, 2006). The existing cardiac catheterization laboratory guidelines addressing bedrest duration are abbreviated and general, lacking in specificity. Sheath size is the major determinant of bedrest duration and commonly ranges from 1 to 2 hours for 4 and 5 French (F) sheaths, and 2 to 4 hours for 6 to 8 F sizes (Bashore et al., 2012). It is understood that certain patient traits including obesity, female gender, and uncontrolled hypertension may place an individual at increased bleeding risk following procedures requiring femoral vascular access. Further activities that may increase bleeding risk are OAC use, bleeding tendencies, coughing, vomiting, straining with elimination, difficult vascular access, multiple femoral vascular procedures, larger sheath sizes, operator experience, hemostasis techniques, use of vascular closure devices, and longer duration of sheaths (Baman et al., 2011). Despite the lack of hard evidence for extended bedrest, varying bedrest duration exists in practice.

Very little research is available on the appropriate amount and role of bedrest duration in avoidance of bleeding complications in the AFCA population. However, there is a substantial body of evidence, including meta-analyses, randomized clinical trials (RCTs), and systematic reviews, on other diagnostic and therapeutic procedures requiring femoral access, including diagnostic cardiac catheterization (DCC), percutaneous coronary intervention (PCI), and percutaneous transluminal coronary angiogram (PTCA). Thus, the evidence-base for this project is post-procedure bedrest duration of patients undergoing DCC, PTCA, and PCI.

Search Strategies

The search strategy was driven by the following PICO question: In patients on NOACs who undergo femoral access procedures, does prolonged bedrest improve outcomes and satisfaction with care?

P (population): Patients taking NOACs

I (interest): Prolonged post-procedure bedrest (12 hours or longer)

C (comparison): Traditional post-procedure bedrest (<8 hours)

O (outcome): Bleeding complications, hematoma, AVF, pseudoaneurysm, back pain, urinary complaints, patient satisfaction

CINAHL, PubMed, and the Cochrane Library databases were searched using various combinations of keywords including femoral vascular access, catheter ablation, cardiac catheteriz(s)ation, bedrest, ambulation, bleeding, hematoma, anticoagulation, electrophysiology study, and atrial fibrillation. On initial searches all dates and study types were searched, then narrowed down to include the past five years, 2008 to 2013, with English language the only limit selected. Further limited searches including searching for randomized controlled trials (RCTs), meta-analyses, and systematic review articles and manually reviewing the reference lists of selected high quality studies.

Upon review of articles regarding bedrest and bleeding complications following femoral vascular access for DCC, PTCA, PCI, and EP studies, the author excluded DCC studies from synthesis, due to the simplicity of the procedure compared to the more involved PTCA, PCI, or electrophysiology study (EPS) or AFCA. The DCC typically uses a smaller vascular access sheath or catheter size (4 French [F] or 6 F), and is of shorter duration than when a patient receives an intervention of balloon angioplasty in PTCA, or stent deployment in PCI. In the PTCA and PCI patients, the larger sheath and catheter sizes required for vascular access and intervention, and procedure duration are more akin to the complex EPS and AFCA procedures. The included studies for synthesis examined outcomes of femoral access site bleeding and hematoma, patient comfort, and some included urinary discomfort as a secondary outcome related to bedrest duration or ambulation time. Figure 1 depicts the flow of the literature search.

Literature Synthesis

Seminal research on the role of bedrest duration consisted of a series of four time-in-bed studies (TIBS). The first two studies were done with patients undergoing DCC, first reducing bedrest duration from 12 to 6 hours (Keeling, Knight, Taylor, & Nordt, 1994), then, reducing time-in-bed from 6 to 4 hours (Keeling, Taylor, Nordt, Powers, Fisher, 1996). These studies supported evidence that shorter time-in-bed following DCC was not associated with an increased risk of bleeding. Patient satisfaction was also improved with shorter post-DCC time-in-bed. Similar results were found with later studies with patients undergoing PTCA and reduced bedrest from 6 to 4 hours (Keeling, Fisher, Haugh, Powers, Turner, 2000) and patients undergoing EPS with reduced bedrest from 4 to 2 hours (Gianakos, Keeling, Haines & Haugh, 2004).

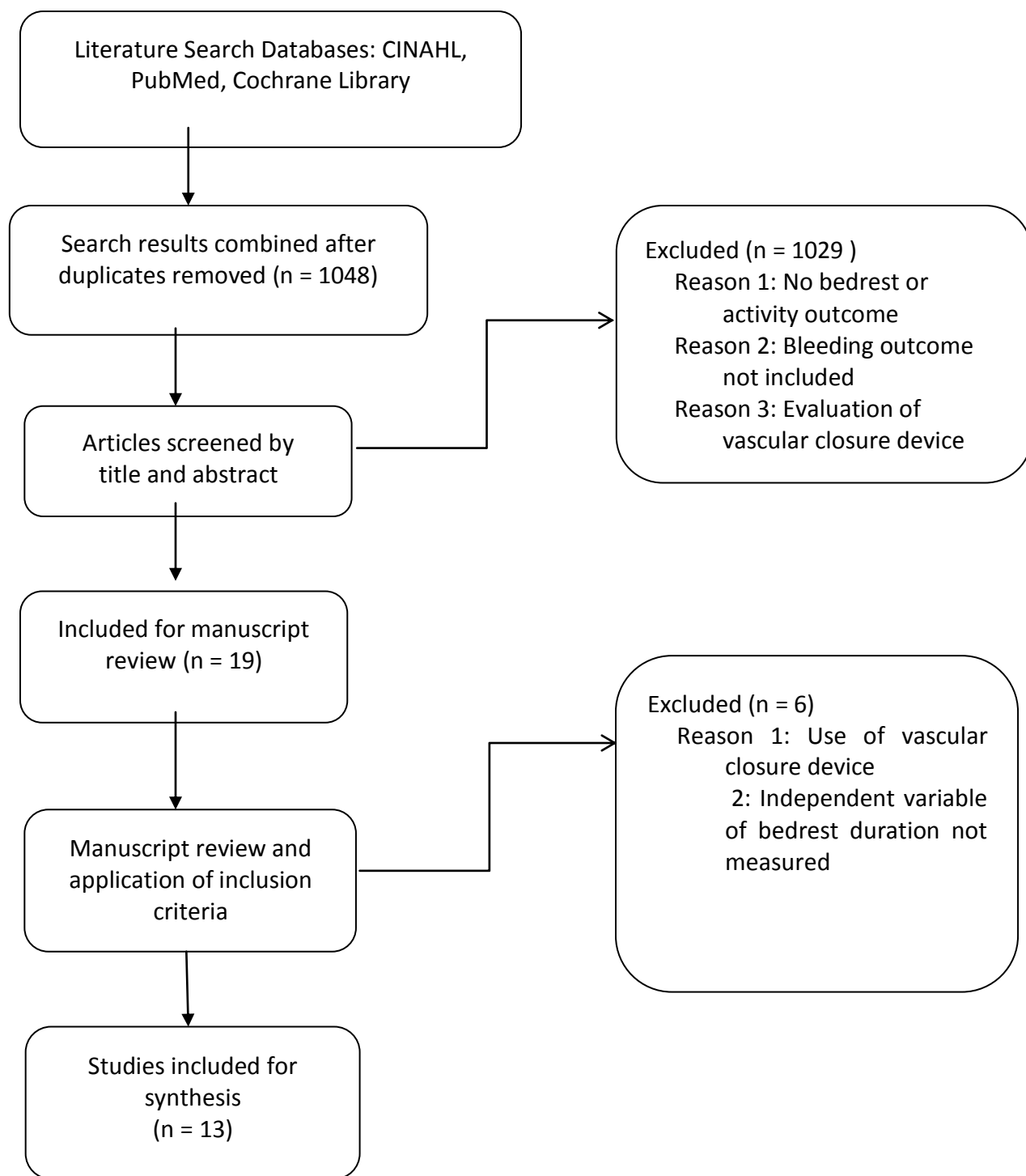


Figure 2.1. Flow diagram of article selection process.

Research syntheses

Since these seminal studies, a plethora of research has been done in this area. Much of the research has been synthesized in several meta-analyses and systematic reviews (see Table 2.1). Three recent meta-analyses of a total of 40 RCTs on shortened bedrest duration following femoral sheath removal in 10,658 patients undergoing DCC or PCI procedures found no effect on bleeding or hematoma formation (Kim et al., 2013; Mohammady Heidari, Sari, Zolfaghari, & Janani, 2013; Tongsai & Thamlikitkul, 2012). These findings echoed those of three earlier systematic reviews of experimental, quasi-experimental, and descriptive studies (Chair et al., 2008; Reynolds, Waterhouse, & Miller, 2001; Vaught & Ostrow, 2001).

Experimental and Quasi-experimental Studies

Ongoing research continues to provide evidence of the safety of early ambulation. A total of nine studies were reviewed and synthesized (see Table 2.2). Table 2.3 provides the criteria used to determine the strength and quality of the evidence.

Similar to the previous research syntheses, there was no difference in bleeding or vascular complications with shortened bedrest duration. In one instance, there was a non-significant increase in bleeding in the longer bedrest (Tagney & Lackie, 2005). There was no difference in urinary complaints or back pain among the groups. Patient satisfaction was not specific to bedrest duration in the included study.

Table 2.1

Research Syntheses of Bedrest Evidence

Author (Year)	Method	Sample	Intervention	Outcome Measurement	Conclusions
Kim et al. (2013)	Meta-analysis	15 RCTs or quasi-experimental studies with 4,785 pts undergoing PCI	Early ambulation	Vascular complications: hematoma formation and hemorrhage at puncture site	No increase in RR ratio of the incidence of hematoma formation nor bleeding at the puncture site based on early ambulation
Mohammady et al. (2013)	Systematic review and meta-analysis	20 RCT's or quasi-experimental studies with 4019 pts undergoing DCC	Different durations (2-24 h) of bedrest before ambulation	Vascular complications Pain Urinary discomfort Patient satisfaction;	Early ambulation (2-3h) had no significant effect on incidence of vascular complications (hematomas reported 7.6% (268 occurrences) and bleeding 2.2% (47 occurrences); back pain was lower in shorter bedrest; decreased urinary discomfort at 4h compared to 12-24 h (mean difference: -1.48; 95% CI: -2.37,-0.59)
Tongsai & Thamlikitkul (2012)	Meta-analysis	5 RCTs with 1,854 pts undergoing PCI	Early ambulation (2-4h) vs Late ambulation (6-10h):	Vascular complications: bleeding, hematoma	Pooled RR of hematoma was 0.82 (95% CI, 0.53-1.28); Pooled RR of bleeding was 1.77(95% CI, 0.87-3.59) Early ambulation after PCI was not associated with an increased risk of hematoma or bleeding and confirmed the findings of earlier studies recommending reduced time in bed following sheath removal from 6-10h to 2-4h
Chair et al. (2008)	Systematic review	18 RCTs or quasi-experimental studies with 4,294 pts undergoing DCC	Varying bedrest duration	Vascular complications: bleeding, hematoma, bruising, pseudoaneurysm Back pain Groin pain Urinary discomfort Patient satisfaction	No benefit related to bleeding and hematoma in longer than 3h bedrest; Less back pain in groups <6h bedrest; Methodological deficiencies in evidence base for generalizability of studies; Standardized, validated tool needed for hematoma measurement;

Author (Year)	Method	Sample	Intervention	Outcome Measurement	Conclusions
Reynolds et al. (2001)	Systematic review	8 experimental, quasi-experimental, and descriptive, studies with 1,352 pts undergoing PTCA 1 survey of 100 hospitals	Early ambulation;	Vascular complications: bleeding, hematoma Pain, comfort; Patient satisfaction	Little existing evidence based research existing; Further large scale studies studies to guide post-PTCA on HOB elevation, walking, and patient comfort
Vaught & Ostrow (2001)	Systematic review	5 experimental, quasi-experimental, and descriptive studies of 235 pts undergoing PTCA 1 survey of 70 hospitals	Bedrest duration	Vascular complications: bleeding, hematoma Pain Patient satisfaction	Decrease in hours of bedrest is safe following PTCA; more research is needed on specific post-procedure interventions and research articles needed on protocols; reliable and valid tool to measure bleeding and hematoma formation; universal pain scale needed;

Table 2.2

Randomized Controlled Trials and Quasi-experimental Studies of Bedrest Post Femoral Access Procedure

Author (Year)	Method	Sample	Intervention/Control	Outcomes and Measures	Results	Quality of Evidence
Chair et al. (2012)	RCT-single blinded	Pts undergoing DCC with unknown sheath size IG: n= 63 CG: n= 74	IG = 4h bedrest CG = 12-24h bedrest	Vascular complications Pain Urinary discomfort Patient satisfaction	1 pt in CG with bleeding Less back pain at 8 hours for IG (OR=0.19, 95% CI, 0.08-0.45, p<0.001); Less "very or unbearable urination discomfort" in IG than CG (OR=0.35, 95% CI, 0.14-0.90, p=0.03) Patient satisfaction no difference	Level I B
Gianakos et al. (2004)	RCT	Pts undergoing EP with 8F or smaller sheath IG: n=31 CG: n= 37	IG = 2h bedrest CG = 4h bedrest	Bleeding Back pain Patient satisfaction	No difference in bleeding incidence among groups Back pain in 2 pts in CG and 1 pt in IG Patient satisfaction findings unclear as pts rated overall care and not specific to bedrest duration	Level II C
Keeling et al. (1994)	RCT	Pts undergoing DCC with unknown sheath size	IG = 6h bedrest CG = 12 h bedrest	Bleeding	No difference in bleeding incidence among groups	Level II C
Keeling et al. (1996)	RCT	Pts undergoing DCC with unknown sheath size	IG = 4h bedrest CG = 6h bedrest	Bleeding	No difference in bleeding among the groups	Level II C

Author (Year)	Method	Sample	Intervention/Control	Outcomes and Measures	Results	Quality of Evidence
Keeling et al. (2000)	RCT	Pts undergoing PTCA with 8F catheter primarily IG: n=51 CG: n= 20	IG = 4h bedrest CG = 6h bedrest	Bleeding	98% of pts did not bleed; Bleeding was associated with higher ACT and re-procedures	Level II C
Searle & Hoff (2000)	Quasi-experimental	Pts undergoing DCC with unknown sheath size IG: n= 680 CG: n=696	IG = 2h bedrest CG = 3h bedrest	Bleeding or hematoma at discharge and 1 week post	IG bleeding in 28 (4%); CG bleeding in 26 (4%); IG bruise at 1 wk- 464 (74%); CG bruise at 1 wk-438 (73%); Late hematoma formation less in IG (p<0.001) and no increase in early bleeds or hematoma formation	Level III B
Schiks et al. (2008)	Quasi-experimental	Patients undergoing PCI or fractional flow reserve (FFR) with 6F sheath IG: n= 329 CG: n = 202	IG = 4h bedrest CG = 10h bedrest	Puncture site complications: hematoma, bleeding, pseudoaneurysm, AVF Patient comfort	9 puncture site complications in IG (2.7%) and 6 in CG (3.0%) p=0.002; Patient comfort not statistically significantly different in groups	Level II A
Tagney & Lackie (2005)	RCT	Patients undergoing DCC or PTCA -with 6F sheath size IG: n = 176 CG: n = 195	IG = 3h bedrest CG = 6h bedrest	Bleeding Hematoma	Bleeding complications increased from 5(2.6%) in CG to 11(6.3%) in IG-not statistically significant (p=0.333); Hematomas: 29 (14.8%) in IG; 19 (10.8%) in CG;	Level I B

Table 2.3

Appraising the Strength and Quality of the Research Evidence

Strength of Research Evidence Rating Scheme	
Level	Type of Evidence
I	Evidence obtained from an experimental study/randomized controlled trial (RCT) or meta-analysis of RCTs
II	Evidence obtained from a quasi-experimental study (cohort study)
III	Evidence obtained from a non-experimental study, qualitative study, or meta-synthesis
Quality Rating Scheme for Research Evidence	
Grade	Research Evidence
A = High	Consistent results with sufficient sample, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence
B = Good	Reasonably consistent results; sufficient sample, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
C = Low Major Flaws	Little evidence with inconsistent results; insufficient sample size; conclusions cannot be drawn

Note. From *Johns Hopkins nursing evidence-based practice model and guidelines* p. 90, by R.P. Newhouse, S.L. Dearholt, S.S. Poe, L.C. Pugh, & K.M. White, 2007. Indianapolis, IN: Sigma Theta Tau International.

Clinical Guidelines

Nursing clinical guidelines by Rolley, Salamonson, Wensley, Dennison, and Davidson (2010) in Australia address peri-procedural care of PCI patients. Although no clear bedrest duration was recommended in the guidelines, times from 2 hours to 4 hours were graded as a "D" recommendation, meaning evidence is weak and recommendations should be applied with caution. Consensus was based on expert opinion only.

Theoretical Framework

The studies synthesized for this literature review cite patient comfort and safety as primary endpoints but none clearly delineate a theoretical framework. Im and Meleis (1999) discussed the disconnect clinicians may feel between grand theories and actual clinical practice of nursing and the need for scholars to consider the increasing patient complexity, diversity and

multiple factor complications. Situation specific theories are defined as theories "that focus on specific nursing phenomena that reflect clinical practice and that are limited to specific populations or to particular field of practice" (Im & Meleis, 1999, p. 13). This approach to developing a situation-specific theory easily translates to care of the AFCA patient and the dynamic nature of evolving knowledge of post procedure bedrest and application of this growing evidence. With the emergence and increasing use of NOACs coupled with the growing practice of AFCA, a clinically specific nursing theory is appropriate for use. The situation-specific theory is put in social and historical context, which clearly is in line with the practice needs of nursing caring for this patient population. Bedrest duration has evolved and shortened in DCC and PCI patients and will continue to evolve in AFCA patients as further research and investigations are performed. A clear connection between research and practice is present in situation-specific theories, and this will be necessary to build the body of knowledge for the appropriate bedrest duration for AFCA on NOACs. Patient diversity and individual traits will limit generalizability of all findings of appropriate bedrest duration as the authors propose in a situation-specific theory (Im & Meleis, 1999).

Summary

Although though there is no evidence to date regarding duration of bedrest post-AFCA and either complications or patient satisfaction, there is compelling evidence regarding other femoral vascular access procedures. Because of the similarities in the procedures themselves with respects to vascular access as well as in the post-procedure precautions, it is reasonable to conclude that the same would be true of the outcomes with respect to bedrest. Evidence supporting NOACs in AFCA with safety and efficacy in the periprocedural time is surfacing, there is a tremendous need to give nursing the tools to care for these patients. As AFCA

becomes more widely performed on patients taking NOACs, literature regarding best nursing practice is crucial to provide high quality patient care. Minimizing patient discomfort including back pain and urinary issues, and safely managing femoral vascular access site complications is tantamount to best nursing practice. This project examines ongoing bedrest practices as a risk factor for complications and satisfaction in patients undergoing invasive femoral venous and arterial access in AFCA while taking NOACs.

Chapter III: Methods

This chapter includes a description of the design setting and sample used in this quality improvement project. This is followed by a discussion of data collection procedures and issues related to the protection of human subjects.

Design

This was a quality improvement (QI) project evaluating primary and secondary outcomes based on the duration of bedrest in patients who have undergone atrial fibrillation catheter ablation while on novel oral anticoagulants.

Setting

The setting for this project was a 249-bed teaching hospital in the southeastern United States. Approximately 15 to 20 patients undergo elective AFCA procedures each month, of which approximately 60% are taking NOACs. The procedures are performed by two electrophysiologists. Immediate post procedure care occurs in a 10 bed holding bay of the cardiac catheterization lab with subsequent transfer to a 23 bed telemetry unit with a 1 to 4 nurse to patient ratio for overnight observation.

Current Practice

Immediately following the procedure, patients are in the post-op holding area while they awaken from anesthesia and undergo sheath removal and manual compression to achieve hemostasis. Post-procedure care is carried out according to standard hospital protocols as directed by individual physician orders. After manual compression and hemostasis is attained, a FemoStop® compression device is applied to the groin with 80mm Hg inflation and 10mmHg reduction hourly over 8 hours (see Appendix A). The duration of bedrest depends on the

physician performing the procedure. Physician A allows his patients to ambulate at the time of FemoStop® deflation and removal. Physician B requires an additional 4 hours of bedrest before ambulation.

Nurse practitioners (NPs) are in-house overnight and are the primary providers as first call during the patient's observation status following the procedure after receiving sign out from the physician. The role of the NP includes entering post-procedure orders, ordering home medications, performing assessments of the puncture site, treating pain, monitoring for bleeding and urinary complaints, and performing the discharge the following morning. The physician rounds on the patient the following morning and issues are generally discussed at that time

The details of the AFCA procedure are recorded on a standard EP Pre/Post Checklist that is not a permanent part of the patient's medical record (see Appendix A). This checklist includes the procedure and the name of the physician performing it, medical history, height, weight, lab results, OAC and when last taken, intraoperative medications and anticoagulants administered. The sheath sizes and locations and times of hemostasis are recorded with ambulation time. Further information recorded on this sheet includes the vital signs, groin/site checks, bleeding complications, FemoStop® management, and pulses. This sheet is used by nursing staff to transition care from the post-op holding area to the telemetry unit where the patient will stay overnight.

Sample

A convenience sample of 30 patients taking NOACs and undergoing AFCA between February 3, 2014 and April 30, 2014 was collected for analysis. Exclusion criteria included difficult vascular access in the EP lab or significant rebleeding requiring additional manual

compression with sheath removal in the holding bay prior to transfer to the nursing unit. All patients undergoing AFCA on NOACs were eligible for inclusion.

Procedures

This quality improvement project did not affect the routine post-procedure care of patients undergoing AFCA. Enrollment of patients took place either pre- or post-operatively in the cath lab holding bay or the patient room. This was determined based on scheduling and flow of patients. An oral consent and signed authorization to access private health information was obtained by either the PI or co-investigator authorized to do so. EP Pre/Post Checklists were collected at the time of discharge by the nurse practitioner and deidentified by the principle investigator (PI) prior to data entry. Each record was assigned a participant code number at that time. Additional information collected by the NP the morning following the procedure using the Post-EP Procedure Assessment and using the same participant code number (see Appendix B). The recorded information included time of ambulation, bleeding complications, and patient complaints of urinary discomfort or back pain.

Final assessment of bleeding outcome and presence of a hematoma was evaluated by direct visualization, palpation, and auscultation of the groin puncture sites after removal of all dressings by the NP. Nursing staff notified NP's during the night if bleeding occurred with first ambulation or was noted with groin checks. The patients' urinary complaints and back pain was evaluated by questioning of patient and nurse at time of NP discharge visit the following morning. Urinary complaints included burning, difficulty with urinating on bedpan, and inability to void requiring urinary catheterization. Back pain was evaluated by the use of pain medication and patient verbalization of complaints of back pain. Bedrest duration following hemostasis was recorded by the nursing staff or NP at time of collection of data sheets on morning of discharge.

The patients on the shortened bedrest track often remained in bed for a prolonged time, not only for bleeding reasons. These data were routine data already collected during routine post-procedure assessment and patient care prior to discharge.

The staff collecting the data was trained by the PI to ensure the completion and retention of the data collection sheets (see Appendix C). Frequent reminders to ask these questions at time of patient discharge and assist in data collection was provided to the NP team involved in this role through flyers (see Appendix D) and verbal cues as well as the posting and distribution of the Post EP Procedure Assessment form in the cath lab holding area, the NP office, and the nursing unit where care for these patients was provided. These questions of the patient were routine questions of current practice by both nursing staff and NPs when discharging the patient.

Protection of Human Subjects and Ethical Considerations

Application to the institutional review board (IRB) was performed and approval was obtained for minimal risk status for one year. Only deidentified data was collected prospectively with no change in usual care practices. The hospital served as the authorized IRB of record for the University of North Florida (UNF) IRB approval. Patients provided an oral consent to participate in the study (see Appendix E) and signed and received a copy for permission to allow investigators access to their personal health information (see Appendix F).

Chapter IV: Results

This chapter includes a description of the sample and delineation of the sample characteristics. This is followed by an overview of the results with respect to primary and secondary outcomes related to duration of bedrest.

Sample Characteristics

A total of 30 patients underwent atrial fibrillation catheter ablation while on novel oral anticoagulants during the study period. Thirty (100%) were invited to participate in the study and 30 (100%) consented. Participants ranged in age from 45 to 77 (M = 66.5; SD = 6.7). Body mass index ranged from 23.2 to 39.2 (M = 30.7; SD = 5.3). The actual time in bed ranged from 6 hours and 9 minutes to 16 hours and 40 minutes (M = 10 hours and 6 minutes, SD = 3 hours, 18 minutes). The majority of the participants were males taking rivaroxaban as their NOAC.

Twenty-two patients (73.3%) were placed on the shortened bedrest track of 8 hours as ordered by the physician, and 8 (26.7%) were on prolonged bedrest ordered for 12 hours. These orders were placed based on physician preference. Because of a variety of factors, the actual length of time in bed varied within both groups. The actual time in bed exceeded the ordered times due to NP, nursing or patient preferences, time that the procedure was completed, and sleeping through the time allowed for ambulation. Thus, 15 patients (50%) were actually on shortened bedrest (≤ 8 hours) and 15 (50%) were on prolonged bedrest (> 8 hours). See Table 4.1 for a description of sample characteristics by actual bedrest duration.

Table 4.1

Sample Characteristics by Actual Bedrest Duration Group

Characteristic	Shortened Bedrest < 8 hours		Prolonged Bedrest > 8 hours	
	N = 22	73%	N = 8	27%
Gender				
Male (N = 23)	17	77%	6	75%
Female (N = 7)	5	23%	2	25%
NOAC				
Rivaroxaban (N = 14)	11	50%	3	37.5%
Apixaban (N = 9)	6	27%	3	37.5%
Dabigatran (N = 7)	5	23%	2	25%

Outcomes**Primary Outcomes**

Primary outcome data were analyzed according to both physician-ordered bedrest duration groups and actual time in bed (see Table 4.2). There were 5 cases of bleeding after ambulation requiring additional bedrest and manual compression. The bleeding occurred in 5 patients: 3 patients in the shortened bedrest track and 2 patients in the prolonged bedrest track. One patient in the shortened bedrest track had a post-operative hematoma from an inadvertent arterial puncture and required additional testing of complete blood count (CBC), but suffered no re-bleeding with shortened ambulation. Of the 5 patients that bled, only 1 was in bed for eight hours or less, and the remaining 4 had bedrest durations exceeding 8 hours (M = 10.6; SD= 3.6) due to the bleeding or reported “oozing.” Two patients from the short track had FemoStop reapplication with additional bedrest.

Secondary Outcomes

Secondary outcome data were analyzed according to ordered and actual bedrest duration groups (see Table 4.3). Secondary outcome measurements included urinary complaints of

Table 4.2

Primary Outcomes by Physician-Ordered Bedrest and Actual Time in Bed

Complication	Physician-Ordered Bedrest				Actual Bedrest			
	≤ 8 hours		> 8 hours		≤ 8 hours		> 8 hours	
	N = 22	73%	N = 8	27%	N = 15	50%	N = 15	50%
Bleeding	3	14%	2	25%	0	0	5	33%
Hematoma	1	4.5%	0	0	1	6.7%	0	0

difficulty requiring catheterization, hematuria frequency, urgency, and pain and back pain while on bedrest. Four patients had urinary complaints: 3 patients on physician-ordered shortened bedrest track, and 1 on prolonged track. Only one patient with a urinary complaint was actually in bed for 8 hours or less ($M = 11$; $SD = 3.1$). Three patients required urinary catheterization (1 with shortened bedrest; 2 with prolonged bedrest) and one patient had burning (prolonged bedrest) with first urination that resolved spontaneously.

Table 4.3

Secondary Outcomes by Physician-Ordered Bedrest and Actual Time in Bed

Complication	Physician-Ordered Bedrest				Actual Bedrest			
	≤ 8 hours		> 8 hours		≤ 8 hours		> 8 hours	
	N= 22	73%	N= 8	27%	N = 15	50%	N =15	50%
Urinary Complaints	2	9%	2	25%	1	6.7%	4	26.7%
Catheterization	2	9%	2	25%	1	6.7%	3	20%
Back Pain	10	45%	0	0	8	53.3%	2	13.3%

Ten patients of the entire sample complained of back pain while on bedrest and were all physician ordered to be on the shortened bedrest track. Two patients were actually in bed longer than 8 hours ($M = 8.8$; $SD = 1.8$). Three patients suffered from chronic back pain, 5 patients rated their pain on a Likert scale from 3/10 to 10/10 and 5 patients had no pain scale rating recorded. One patient required IV narcotics and the remaining patients were treated with oral

medications, repositioning, and ambulation. One patient complaining of back pain remained in bed for 14 hours at the nurse's recommendation.

Associations between Actual Bedrest Duration and Outcomes

Fisher's Exact test showed no statistically significant difference in bleeding outcomes by actual bedrest duration group ($p=0.39$), gender ($p=0.56$) or specific NOAC ($p=0.27$). Similarly, the Wilcoxon rank sum found no significant difference in bleeding by age ($p=0.65$), or BMI ($p=0.7$).

Fishers' Exact test showed no statistically significant difference in back pain outcomes by gender ($p=0.66$) or NOAC ($p=1.0$). Similarly, the Wilcoxon rank sum test found no statistically significant difference in back pain by age ($p=0.28$) or BMI ($p=0.96$). There was near statistically significant difference in back pain by actual time in bed ($p=0.07$). Fishers' Exact test showed no statistical significant difference in urinary complaints by specific NOAC ($p=1.0$), and Wilcoxon rank sum showed no statistical difference on absolute time in bed ($p=0.46$).

Summary

This study was small and underpowered yet is the beginning of gathering data about outcomes of bleeding, urinary complaints, and back pain on patients undergoing AFCA on NOACs. There was no statistically significant advantage to prolonged bedrest duration related to bleeding. No adverse events were recorded with the shortened bedrest patients in the immediate post-operative times, and bleeding occurred almost equally in both tracks of patients. There was no clear advantage to shortened bedrest in terms of back pain or urinary complaints.

Chapter V: Discussion

Bedrest duration following AFCA is variable and evidence is lacking for the optimal time needed to minimize bleeding complications. The question is further compounded by the peri-procedural use of NOACs and limited knowledge exists on potential bleeding complications. This project to evaluate bedrest duration and bleeding among AFCA patients taking NOACs was undertaken to add to the lacking body of evidence to guide best nursing practice. The goal was to compare bleeding differences based on bedrest duration following the procedure. This chapter presents a discussion of the findings of this project in the context of previous evidence and a delineation of the limitations of the project. This is followed by identification of implications for clinical practice and for future research.

Relation to Other Evidence

The literature review found no evidence to support an established amount of bedrest in the AFCA patient population, but a plethora of high-level research in a similar population of cardiac catheterization and PCI patients with progressively shortened bedrest duration was reviewed. The existing research was exhaustive and conclusive that shortened bedrest duration from over 12 hours reduced to less than 4 hours, was safe and efficacious following both DCC and PCI procedures with femoral vascular access (Chair et al., 2008; Kim et al., 2013; Mohammady et al., 2013; Tongyai & Thamlikithul, 2012). In similarity to prior research, the current study, comparing 8 hours to longer than 8 hours showed no difference in bleeding outcomes with shortened bedrest. The 8 hour timeframe was studied based on performing physician preference of post procedure care. The literature on early ambulation in DCC and PCI patients has been evolutionary and the current study begins the body of knowledge necessary to

investigate bedrest duration and bleeding in the AFCA patient population (Keeling et al., 1994; Keeling et al., 1996; Keeling et al., 2000; Reynolds et al., 2003; Searle & Hoff, 2000; Vaught & Ostrow, 2001).

Similarly, the current study results were not statistically significant for urinary complaints related to bedrest duration as in prior research (Chair et al., 2012). In the current study, urinary complaints were present almost equally in the shortened and prolonged bedrest track patients. Back pain was statistically significant in the physician-ordered shortened bedrest track patients in the current study, and near statistical significance based on actual time in bed. Back pain was the most common complaint reported among all patients, similar to previous research (Chair et al., 2012; Gianakos et al., 2004).

One difference among the procedures is that DCC and PCI access involves a femoral artery access with AFCA requiring femoral venous access. Both procedures are cared for pre and post by the same nursing staff in the same catherization lab holding area. Femoral access vascular hemostasis is achieved similarly following sheath removal with the same general bedrest, limb immobilization, and limitations of head of bed elevation restrictions on both sets of patients. Both procedures may require anticoagulation peri-procedurally, thus increasing the risk of bleeding.

There was no statistically significant advantage to prolonged bedrest duration related to bleeding. No adverse events were recorded with the shortened bedrest patients in the immediate post-operative times, and bleeding occurred almost equally in both tracks of patients. There was no clear advantage to shortened bedrest in terms of back pain or urinary complaints.

Limitations

The sample size is small ($n=30$) and the results are not generalizable, but adequate to portray clinical practice at this particular facility and are representative of the population undergoing the procedure at this hospital. There are many possible confounding variables with this study, including use of IV unfractionated heparin in varying doses, sheath size, physician technique, procedure duration time, number of prior femoral vascular access procedures, and varying times of medication administration peri-procedurally. Other confounding variables may include patient characteristics of age, gender, chronic back pain, and BMI.

Defining bleeding and hematoma consistently was a limitation of the study. With multiple NPs, nurses, and cath lab staff involved in caring for these patients, the perception and definition of bleeding was variable. A valid and reliable hematoma measurement tool was lacking and reliance upon accurate measurement by the nurse or NP was required in this study. Also, bleeding outcome could be better quantified to determine if it was significant to require additional bedrest. Bleeding is a subjective nurse measurement and some nurses viewed any blood on the dressing, even if dried, as a reason to postpone patient ambulation.

A perception of bleeding complications with patients on NOACs continues to be prevalent in this facility. In some cases, nursing would lengthen the bedrest duration based on their beliefs. The time of the procedure also likely affected the time of ambulation. Often, the patient would be allowed out of bed at midnight but would choose to sleep through until the morning.

Pain assessment and measurements were also variable and lacking in detail. Some nurses recorded the pain complaints, scales to assess, treatments, and responses to treatment, and others were not clearly recorded or were lacking details. Due to the nature of the procedure and the positioning required, many back pain complaints may have been overreported. Similar problems

existed for recording urinary complaints and treatments. There was not a clear way to report and record urinary complaints and treatments.

Implications for Practice

The findings support the hypothesis that shorter, or traditional bedrest duration of 8 hours, compared to prolonged bedrest of 12 hours or longer, did not increase bleeding complications. These findings are useful in guiding nursing practice in caring for the patients post procedurally. A standardized, post AFCA bedrest duration of 8 hours is sufficient to maintain hemostasis in patients on NOACs. There was no benefit to maintain bedrest longer than 8 hours to minimize bleeding complications in this study sample. There was no less reported back pain in the shortened back pain track and urinary complaints were similar in both groups.

The implications for nursing practice are important in changing practice in our institution to a standard of post procedure AFCA bedrest duration care. The results represent hard data that lengthened bedrest does not change the bleeding outcomes in this patient population. This data collection will be continued through the year and further analyzed by the stakeholders to collectively determine a standard of care. The findings will be submitted for presentation at the annual Heart Rhythm Society in May 2015 and submitted for publication in electrophysiology nursing literature.

Implications for Research

The implications for research include the need for well-designed randomized controlled trials to evaluate well-defined variables in the AFCA patient population and the amount of bedrest duration needed to minimize bleeding complications. This QI project should be the beginning of further research to evaluate post procedure bedrest duration in AFCA patients on NOACs. Future research may further analyze the role of intra-procedural use and amounts of

unfractionated heparin, femoral access sheath sizes, patient characteristics of age, gender, BMI, and chronic back pain. A reliable and validated bleeding and hematoma measurement tool would be useful to quantify bleeding. Consistent use of a Likert pain scale for back pain would help measure this outcome more accurately. Assessment of treatment response to interventions of back pain should also be measured. Further interventions to minimize back pain in all post operative AFCA patients should be investigated in future research, as this problem was more common in shorter bedrest durations. Clear orders of bedrest duration tracks should be standardized to minimize confusion among nursing and provider staff with sufficient and ongoing education to ensure understanding.

Conclusion

The most important finding in this QI project was identification of the lack of evidence on bedrest duration following the AFCA. The project further studied the population of patients taking NOACs, as these drugs are quickly replacing the use of warfarin. With the increasing prevalence of AF and the widely performed AFCA as a viable treatment option, nursing practice must strive to offer evidence based care of these patients. As the AFCA procedure continues to evolve with increased use of NOACs, smaller vascular access sheath sizes, shorter procedure times, and more experienced operators, nursing care must be challenged to provide the best care of these patients. As bedrest duration has shortened over decades in the DCC and PCI patient populations while maintaining safe practice, it is hoped that the same may occur with AFCA patients.

Appendix A

Procedure Checklist

ATE: _____

REMEMBER TO WASH YOUR HANDS PRE & POST PT CONTACT
EP PRE/POST CHECKLIST

HOLDING BAY # _____	ALLERGIES:	
	(PT STICKER)	
	FAMILY CELL PHONE # _____	
Primary RN _____	EP PROCEDURE PHYSICIAN: _____	PREVIOUS: EP STUDY/CV/LOOP
		ABLATION: AFIB/ PVC/ VT/ SVT/ AT/ AFLUTTER
	EP PROCEDURE: _____	DEVICE: PACER/ ICD/ BIV: BOSTON SCI/ MDT/ ST. JUDE
	OP _____ IP RM _____	LEADS: ATRIAL / RV / LV
		DATE OF IMPLANT: _____
HISTORY	METAL IMPLANTS: NO _____ YES _____ LOCATION: _____	
	PRIOR HX:	
	HYPERTENSION	DIABETIC: DIET/ORAL/INSULIN
	HYPERLIPIDEMIA	VALVE DISEASE: AORTIC/MITRAL/TRICUSPID
	HYPERTRIGLYCERIDEMIA	VALVE REPAIR/REPLACEMENT
	PVD	
	CHF NYHA CLASS I II III IV V	HISTORY OF ARRHYTHMIAS _____
	PERICARDIAL EFFUSION	
	CONGENITAL HEART DISEASE	OTHER:
	RENAL DISEASE	SLEEP APNEA
	CARDIAC DISEASE	GERD
	CAD	HYPOTHYROIDISM/HYPERTHYROIDISM
	MI	CVA
	CABG	LUNG DISEASE
	PULM EMBOLI	CANCER
	CARDIOMYOPATHY: ISCHEMIC _____ NONISCHEMIC _____ EF _____ %	
PRE PROCEDURE INFORMATION	HT _____ CM WT _____ KG	PRE PROCEDURE PULSES
	DATE OF LABS: _____	LT PULSES: DP _____ PT _____ RADIAL _____
	HGB _____ NA _____	RT PULSES: DP _____ PT _____ RADIAL _____
	HCT _____ K+ _____	
	RBC _____ CL _____	COUMADIN LAST DOSE _____ MG on: DATE _____
	WBC _____ GLU _____	LOVENOX LAST DOSE TAKEN _____
	PLAT _____ CREAT _____	PRADAXA LAST DOSE TAKEN: _____
	PT _____ BUN _____	
	INR _____ CO2 _____	EMAR/ PER PT :PRE PROCEDURE/ AM MEDS GIVEN or TAKEN
	PTT _____ GFR>60 or _____	_____
	ACCUCHECK @ _____	_____
	INT(size and location): _____ G/ RT ARM/ LT. ARM	_____
	SODIUM CHLORIDE @ KVO	_____
PROCEDURE MEDS GIVEN	***** SEE ANESTHESIA RECORDS FOR ALL SEDATION ON CRNA PROCEDURES*****	
	SEDATION GIVEN:	
	PROPOFOL _____ mg	HEPARIN _____ units
		CONTRAST _____ mL
	VERSED _____ mg	IV Fluids _____ mL
		Other Meds:
	FENTANYL _____ mcg	ANCEF _____ g @ _____
	ISUPREL _____ mcg	VANCOMYCIN 1g @ _____
	FORM NOT PART OF PATIENT RECORD- DO NOT PLACE IN CHART	
	Revised 06/29/11	

POST PROCEDURE INFORMATION

CV BED NEEDED: YES/ NO Room# _____		
SDDC: NO _____ YES _____ DISCHARGE TIME _____		
NEED CXR _____ NEED EKG _____		
ACT _____ @ _____ (time)		
1) _____	FRENCH SHEATH(S) REMOVED FROM _____ W/ NEPTUNE PATCH @ _____ (time) HEMOSTASIS TIME: _____ HEMATOMA PRESENT: YES / NO	
2) _____	FRENCH SHEATH(S) REMOVED FROM _____ W/ NEPTUNE PATCH @ _____ (time) HEMOSTASIS TIME: _____ HEMATOMA PRESENT: YES / NO	
3) _____	FRENCH SHEATH(S) REMOVED FROM _____ W/ NEPTUNE PATCH @ _____ (time) HEMOSTASIS TIME: _____ HEMATOMA PRESENT: YES / NO	
SAFEGUARD APPLIED to LT GROIN: _____ RT GROIN: _____ (PLEASE SEE ATTACHED SAFEGUARD SHEET)		
FEMSTOP APPLIED to LT GROIN: _____ RT GROIN: _____ FEMSTOP START TIME: _____		
AMBULATION TIME: _____		
WOUND CLOSURE TIME: _____		
PRESSURE DRESSING(S) APPLIED to LT CHEST SITE: _____ RT CHEST SITE: _____		
ARM SLING: NO _____ YES _____ PACEBRACE: S M L		
PULSES POST PROCEDURE		
RT PULSES: _____ DP PT RADIAL		
LT PULSES: _____ DP PT RADIAL		
TIME FOR VITAL SIGNS AND GROIN / SITE CHECKS/PULSE CHECKS		
VS q 15 MIN X 4	VS q 30 MIN X 2	VS q 1HR X 4
1) _____	1) _____	1) _____
2) _____	2) _____	2) _____
3) _____		3) _____
4) _____		4) _____
FEMOSTOP CHECKS / PRESSURE REDUCTION TIMES/PULSE CHECKS		
1) 80mmHg at _____ (time)	3) 60mmHg at _____ (time)	5) 40mmHg at _____ (time)
2) 70mmHg at _____ (time)	4) 50mmHg at _____ (time)	KEEP PRESSURE at 40mmHg FOR q 4HRS and remove
Revised 06/29/11		

Appendix B

Patient Measurement Outcomes

Question	Y	N	Describe
Did pt have rebleed requiring add'l bedrest?			
Hematoma formation larger than 5 cm?			
Was add'l testing, blood transfusion, or surgical consult required?			
Did pt complain of back pain while on bedrest restriction? -1-10 Pain scale to describe most severe pain			
Did patient have complaints of urinary burning, frequency, bleeding, inability to void, and/or reinsertion of urinary catheter			

ACTUAL TIME OF AMBULATION _____

PATIENT BMI _____

ADDITIONAL COMMENTS _____

CATH LAB STAFF: PLEASE ATTACH TO EP/CATH LAB HANDOFF SHEET (PURPLE WORKSHEET) AND INCLUDE WHEN PT TRANSFERS TO FLOOR

FLOOR NURSING STAFF: PLEASE GIVE THIS SHEET TO CARDIOLOGY ARNP DAY OF DISCHARGE OR PLACE IN COLLECTION BIN AT 2N NURSING STATION

QUESTIONS PLEASE DIRECT TO: LYNN MCWHIRTER, PI –OR–

CO-INVESTIGATORS: *Not a part of permanent patient record*

Patient label

Date

Appendix C

NP QI Project Training

Novel Oral Anticoagulants: Bedrest and Bleeding in Patients Undergoing

Atrial Fibrillation Catheter Ablation

No change in practice is required for this project.

-Physician 1 patients will continue on standard post-procedure protocol of bedrest until FemoStop pressure is completed at 8 hours following femoral vascular access hemostasis.

-Physician 2 patients will remain on bedrest an additional 4 hours following FemoStop pressure completion for a minimum of 12 hours.

1) Enroll patients undergoing AFCA on NOACs for inclusion into project-no informed consent required

a) Exclusion criteria:

-Difficult vascular access reported by physician

-Rebleeding or hematoma prior to transfer to floor as reported by nursing staff

2) Collect purple EP worksheet and 2nd page questionnaire at time of discharge

3) Review questions and answer/complete from review of chart

4) Place forms in "labeled collection bin" in PI file cabinet

Appendix D

Nursing Staff Information

AFib Ablation Patients Bedrest Duration Study
Of Patients on Novel Oral Anticoagulants
(Dabigatran, Rivaroxaban, Apixaban)

- Study purpose
 - To standardize post afib ablation bedrest
 - Evaluate bleeding outcomes in different bedrest durations among afib ablation pts on NOACs
 - 3 month study: Feb, March, April
 - Secondary measurements: Back pain, urinary complaints
- Usual care of patients
 - Physician A patients remain on bedrest for **8 hours** following sheath removal and hemostasis
 - Physician B patients remain on bedrest for **12 hours** following sheath removal and hemostasis
- Please write time patient ambulated OOB on handoff worksheet
- Additional questions to be asked at time of discharge and recorded on attached sheet
 - Did pt have rebleed requiring add'l bedrest?
 - Did pt have hematoma >5 cm?
 - Was add'l testing, blood transfusion, or surgical consult required?
 - Did pt complain of back pain while on bedrest restriction?
 - Use 1-10 VAS Scale to rate
 - Did pt have urinary complaints: inability to void, require I&O cath, burning, frequency, bleeding?
- Please save purple handoff sheets and questions/answers in bin at 2N A nursing station for collection or give to a study investigator
- PI

Co-Investigators:

Appendix E

Oral Consent Script

Protocol Title: Novel oral anticoagulants: Bedrest duration and bleeding among atrial fibrillation ablation patients

IRB #:XXXXXX

Principal Investigator: XXXXXXX

You are being asked to participate in a research study about bleeding outcomes, back pain, and urinary complaints in atrial fibrillation ablation patients taking novel oral anticoagulation.

If you agree to participate you will be asked to answer simple questions about back pain and urinary complaints. Your age, gender, and body mass index will be recorded as well as your answers to the questions. If you had bleeding from your access sites, this will be recorded. We will not link the information to your identity and you will remain anonymous. You will not receive payment for your participation.

The risks associated with the research study are not increased. These are the questions we would ask if you are not included in this study project. Your care will remain the same whether you are in the study or not. There should not be an increase in your time, discomfort, or confidentiality if you agree to participate.

The benefits which may reasonably be expected to result from this research study will not directly affect your stay but it is hoped to streamline care in the future

Please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. Specifically, your current or future medical care at the XXXX will not be jeopardized if you choose not to participate.

If you have any questions about this research study you can contact me at 555-5555. If you have any concerns, complaints, or general questions about research or your rights as a participant, please contact the XXX Institutional Review Board (IRB) to speak to someone independent of the research team at 555-555-5555 or toll free at 555-555-5555.

Appendix F

HIPAA Authorization to Use and Disclose Protected Health Information

Name and Clinic Number

TITLE

Novel oral anticoagulants: Bedrest duration and bleeding among atrial fibrillation ablation patients

IRB # XXXXXXX

RESEARCHER

Lynn McWhirter and colleagues

PROTOCOL LAST APPROVED BY IRB

January 31, 2014

THIS FORM APPROVED

January 31, 2014

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission. You will be given a copy of this form.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

This information will be used and/or given to others to:

- • Do the research. Report the results. See if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Your health information may be used or shared with:

- XXXXX research staff involved in this study.

Your health information may also be shared with:

- The XXXXX Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

Protection of your health information after it has been shared with others:

XXXX asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside XXXX, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Page 1 of 2

This Form Approved: January 31, 2014

IRB 14-XXXX

Not To Be Used After: January 30, 2015

IRB FORM XXX

HIPAA Authorization to Use and Disclose Protected Health Information

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study. Your decision won't change the access to medical care or any other benefits you get at XXXX now or in the future.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

XXXX Office for Human Research Protection ATTN: Notice of Revocation of Authorization
XXXXX

Alternatively, you may cancel your permission by emailing the XXX Clinic Research Subject Advocate at: XXXXX

Please be sure to include in your letter or email:

• • •

The name of the Principal Investigator, The study IRB number and /or study name, and Your contact information.

Your permission lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.

Printed Name of Participant

Signature of Participant

X

Date of Signature

Printed Name of Representative Signing for Participant (if applicable)

Representative's Relationship to Participant (if applicable)

Signature of Representative Signing for Participant (if applicable)

X

Date of Signature

Page 2 of 2

This Form Approved: January 31, 2014

IRB 14-XXXX

Not To Be Used After: January 30, 2015

IRB FORM 10

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VITA

Lynn McWhirter, RN, MSN, ARNP-BC, FNP, DNP Student, received a Bachelor of Business Administration in 1984 at the University of North Florida (UNF) in Jacksonville, Florida. After several years of employment in sales and marketing in private industry, she returned to school to pursue nursing, completing her Associates' degree in Nursing from Florida Community College at Jacksonville in 1991. She practiced bedside nursing, focusing on adult cardiovascular disease patients primarily from 1992 until 2006, in both acute care and home health settings. She assumed leadership and management roles in her nursing career in both the hospital and home health. Lynn completed her Bachelors' degree in nursing in 2004 from UNF, and continued to complete her Masters' degree in nursing as a Family Nurse Practitioner in 2006. Her Masters' project was a literature review on the quality of life of sleeping partners of patients with obstructive sleep apnea. She worked as adjunct faculty at UNF teaching undergraduate nursing students. Lynn has focused her advanced practice in cardiology, currently employed at Mayo Clinic, Florida, in department of cardiovascular diseases. Lynn is seeking to complete her Doctorate of Nursing Practice at UNF in August 2014. Her doctoral project compared bedrest duration and bleeding among atrial fibrillation catheter ablation patients taking novel oral anticoagulants.