2018

Evaluating Impedance Monitoring to Reduce Hospital Readmissions for Patients with Heart Failure with Reduced Ejection Fraction: An Integrative Review

Abigail Newton
ajaustin@liberty.edu

EVALUATING IMPEDANCE MONITORING TO REDUCE HOSPITAL READMISSIONS FOR PATIENTS WITH HEART FAILURE WITH REDUCED EJECTION FRACTION: AN INTEGRATIVE REVIEW

A Scholarly Project

Presented to the

Faculty of Liberty University

In Partial Fulfillment of the Requirements for the Degree of

Doctor of Nursing Practice

By

Abigail Jean Newton MSN, RN

Scholarly Project Chair:

Dr. Dorothy Murphy, DNP, FNP-BC, Professor of Nursing

EVALUATING IMPEDANCE MONITORING TO REDUCE HOSPITAL READMISSIONS FOR PATIENTS WITH HEART FAILURE WITH REDUCED EJECTION FRACTION: AN INTEGRATIVE REVIEW

A Scholarly Project

Presented to the

Faculty of Liberty University

In Partial Fulfillment of the Requirements for the Degree of

Doctor of Nursing Practice

By

Abigail Jean Newton MSN, RN

EVALUATING IMPEDANCE MONITORING TO REDUCE HOSPITAL READMISSIONS FOR PATIENTS WITH HEART FAILURE WITH REDUCED EJECTION FRACTION: AN INTEGRATIVE REVIEW

A Scholarly Project

Presented to the

Faculty of Liberty University

In Partial Fulfillment of the Requirements for the Degree of

Doctor of Nursing Practice

By

Abigail Jean Newton MSN, RN

Scholarly Project Chair Approval:

Dr. Dorothy Murphy, DNP, FNP-BC, Professor of Nursing, August 3, 2018

ABSTRACT

Congestive Heart Failure (HF) is a chronic progressive cardiac disorder with high mortality rates and is the number one reason for hospital readmission in the United States. More than 5 million Americans live with HF with more than 900,000 new diagnoses annually. The likelihood of developing HF increases with age making it the most common primary diagnosis for patients over age 65. HF has a significant impact on quality of life, with depression being a common comorbid condition. Thoracic impedance monitoring has shown to reduce exacerbations and hospitalizations in patients with HF. This project evaluated the literature related to impedance monitoring in the management of HF. The projected outcome for this project is to demonstrate the state of evidence regarding the effect of impedance monitoring on 30 day hospital readmission rates.

Keywords: impedance monitoring, heart failure, readmissions, costs, transitions theory, and quality of life

Acknowledgements

To my Lord and Savior, who loves me and has a plan for me. Through faith in Him, He is an anchor in all things. To my husband, who continually supports me in my endeavors and encourages me to be the person God wants me to be. To my family, who believes in me and prays for me. To my faculty and preceptors who spent countless hours teaching me. To my cohort, we spent hours of time studying together over the past three years and have formed a close friendship. And, to my Scholarly Project Chair, who encouraged me to pursue the DNP before I even attempted post-graduate school and who has helped me to grow academically and as a clinician.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

ADHF:	Acute Decompensated Heart Failure
CRT-D:	Cardiac Resynchronization Therapy with Defibrillator
ICD:	Implanted Cardio-defibrillator
EHRA:	European Heart Rhythm Association
HF:	Heart Failure
HFrEF:	Heart Failure with Reduced Ejection Fraction
HFpEF:	Heart Failure with Preserved Ejection Fraction
HRS:	Heart Rhythm Society
MLWHF:	Minnesota Living With Heart Failure Questionnaire
NYHA:	New York Heart Association
PAP:	Pulmonary Artery Pressure
U.S.:	United States

Evaluating Impedance Monitoring to Reduce Hospital Readmissions for Patients with Heart Failure with Reduced Ejection Fraction: An Integrative Review

Heart Failure (HF) is a chronic progressive cardiac disorder with high mortality rates and is the most frequent reason for hospital readmission in the United States (U.S.) (Ivany & White, 2013). More than 5 million Americans live with HF with more than 900,000 new diagnoses annually (CDC, 2016). The likelihood of developing HF increases with age making it the most common primary diagnosis for patients over age 65 (CDC, 2016). About half of all HF diagnoses are heart failure with reduced ejection fraction (HFrEF) (Savarese & Lund, 2017). Thoracic impedance monitoring is a tool that is used to identify and predict heart failure exacerbations and prevents hospital readmissions (Franchuk, 2017). On average, the fluid index of impedance monitoring starts to rise 14 days prior to symptom onset (Yu, et al., 2005). Impedance monitoring in patients with HFrEF is not considered the standard of care despite there being evidence to support its use. The current recommendation for impedance monitoring frequency is every 3-12 months (Wilkoff, et al., 2008). This scholarly project sought to evaluate the state of evidence regarding more frequent impedance monitoring in patients with HFrEF at high-risk for hospital readmission who have an existing implanted cardiac device with impedance monitoring capability.

Background

HF is a chronic progressive cardiac disorder that is characterized by the reduced ability of the heart to pump and/or fill with blood, which results in inadequate cardiac output to meet the metabolic demands of the body (Savarese & Lund, 2017). HF has been recognized as a global pandemic and affects nearly 26 million people worldwide and nearly 6 million people in the U.S. (Savarese & Lund, 2017). The likelihood of developing HF increases with age making it the

most common primary diagnosis for patients over age 65 (CDC, 2016). Every year in the U.S. there are over 900,000 new cases of HF. Heart disease is the leading cause of HF (Savarese & Lund, 2017). The prevalence of developing HF is projected to rise because of the ageing population which will likely result in increased hospitalization rates and health care costs (Savarese & Lund, 2017). Alternative treatment and therapies are needed (Savarese & Lund, 2017). HF is classified into three subtypes according to left ventricular function: HFrEF, HF with preserved ejection fraction (HFpEF), and HF mid-range ejection fraction (HFmEF). The diagnostic criteria for HFrEF is left ventricular ejection fraction (LVEF) <35%. The diagnostic criteria for HFpEF is LVEF 55-65%. The diagnostic criterion for HFmEF is LVEF 40-55% (Nadruz, 2016). This scholarly project will be focusing on patients with HFrEF.

Due to the chronic nature of HF, it is difficult to medically and self-manage. Additionally, there are a variety of etiologies that can result in HF with risk factors including heart disease, smoking, and hypertension (CDC, 2017). Diagnostics that are currently used to assist in identifying and monitoring HF include biomarkers such as the b-type natriuretic peptide, echocardiography, 12-lead electrocardiography, echocardiography, and radiography (Coller, Campbell, Krum, & Prior, 2013). A combination of therapies and disciplines is needed to provide optimal care. Patient participation and understanding is critical to positive outcomes (Riley & Masters, 2016). Lifestyle changes that often need to be made include a low sodium diet, fluid restrictions, and daily weight monitoring (AHA, 2017). Patients are often prescribed up to five medications, which are considered guideline-directed medical therapy. These medications include a diuretic, selected beta-blockade, ace-inhibitor, aldosterone antagonist, and sometimes digoxin (AHA, 2017). Many HF patients have a history of other cardiac illness such as myocardial infarction, hypertension, and arrhythmia. The diagnosis of HF can be very difficult

for patients to cope with and depression is a common comorbid condition. Nearly one in five patients with HF also have a diagnosis of depression (Mbakwem, Aina, & Amadi, 2016). A diagnosis of HF directly impacts a patient's quality of life and is a major transition in a patient's life. Hospital admissions and readmissions can be indirectly related to quality of life, so improvement processes around readmission reduction are multifocal to reduce costs and improve quality of life.

One of the major reasons why there is so much emphasis on reduction of readmissions is because patients with HF who suffer from a 30 day readmission have a worse prognosis (Tung, et al., 2016). This underscores the importance of reducing readmissions as a means to improve HF outcomes (Tung, et al., 2016). Early identification of acute decompensated HF (ADHF) allows for early intervention and management. Methods for managing patients on an outpatient basis are continuing to be explored for patients with HF. Intravenous diuretic therapy is used as a more aggressive outpatient treatment option (Buckley, et al., 2016). Ideally, identification of ADHF happens early and treatment can be started quickly in the outpatient environment, preventing a readmission (Buckley, et al., 2016). Impedance monitoring is a way to identify patients who need early intervention for HF. Other interventions that can be implemented early for patients with HF include quality of life assessment, patient education on self-care behaviors, and referral to transitional care programs, such as home health care (Feltner, et al., 2014).

Patients with HF undergo altered quality of life due to serious physical limitations and decreases in functional capacity (Marques de Sousa, dos Santos Oliveira, Oliveira Soares, Amorim de Araújo, & dos Santos Oliveira, 2017). Awareness of a patient's thoracic impedance can enable clinicians to monitor quality of life in their patient population in addition to treatment

options. The Minnesota Living with Heart Failure Questionnaire (MLWHF) is the most widely used quality of life assessment tool for patients with HF (Marques de Sousa, et al., 2017).

Patient education, with self-care being critical to positive outcomes, is also an integral part of HF management. Low sodium diets (He & MacGregor, 2011), monitoring of daily weights, medication adherence, fluid intake, and exercise are just a few of the self-care techniques that are taught to patients with HF (AHA, 2014). Management of symptoms through a low sodium diet is a finding that has been consistent in a large number of studies and He & MacGregor (2011) conducted a meta-analysis of outcomes trials to confirm this finding. This study's purpose was to highlight that a behavior can reduce cardiovascular risk and it's primary objective was to review the importance of reducing salt intake on cardiovascular health. The World Health Organization (WHO) supports this consensus and salt reduction is one of the top three priorities to tackle the non-communicable disease crisis (He & MacGregor, 2011). Reduction of salt intake is one of the primary education points in symptom management for patients with heart failure (CDC, 2016).

Another component to care transitions is the utilization of home health services. HF patients that are discharged to a home health care service and who have early physician follow-up have been shown to have a reduced readmission rate (Murtaugh, et al., 2017). Additionally, patients with HF who received interventions based on their thoracic impedance monitoring combined with home health care had fewer 30 day readmissions than patients who only received home care (Shapiro, et al., 2017).

Because HF is increasing in prevalence and is associated with high mortality and morbidity there is significant associated personal and societal burden. Functional decline and increasing dependence on others mark the transition for a more palliative approach with goals of care around quality of life and symptom management. Patients and caregivers recognize that heart

failure is a series of transitions (Jones, Nowels, Sudore, Ahluwalia, &Bekelman, 2015). Transition theory has been identified as an applicable nursing theory that offers hope during this time of transition. This theory helps clinicians, patients, and families adjust to the challenges of a diagnosis of HF and navigate the illness trajectory. Maintaining Hope in Transition is a theoretical framework stemming from Transitions Theory and is useful in the care of patients with HF. Key factors described include acknowledging circumstances, restructuring reality, dealing with vulnerability, achieving normalization, and resolving uncertainty. Incorporating theory into the plan of care can help assist clinicians and providers with care planning and focused interventions for patients and families from diagnosis to advanced stages (Davidson, Dracup, Phillips, Padilla, & Daly, 2007). It is important to consider each care option that is available to a patient.

Palliative care is another important option to consider in the management of heart failure. Many clinicians are still learning the palliative care needs of their patients. This integrative review includes this topic in the discussion because of the focus on transitions of care. Impedance monitoring can be utilized to help clinicians manage HF and may guide the treatment plan even towards palliative care in the event that advanced therapies are not options and HF has negatively impacted the quality of life of the patient and their family (Ivany & White, 2013). This poor prognostic diagnosis encourages the need to continue to study ways to improve outcomes for patients with HF. Despite the chronic and progressive nature of HF there are barriers to providing palliative care. It is challenging dealing with the diagnosis of heart failure, and many patients are alarmed by the term palliative care (Ivany & White, 2013).

Some patients with HF have been implanted with cardio-defibrillators (ICD) or cardiac resynchronization therapy with cardio-defibrillator (CRT-D) devices. For nearly 10 years experts

have been recommending the use of pacemaker technology in the management of cardiac patients (Toogood, 2007). It is estimated that over 3 million Americans have a pacemaker, and nearly 600,000 pacemakers are implanted annually (Wood, & Ellenbogen, 2002). Thoracic impedance is a function of many pacemakers and ICD's that are used today. ICD's are indicated in patients with HFrEF with LVEF less than 35% and cardio-resynchronization therapy with defibrillator (CRT-D) are indicated for LVEF less than 35%, New York Heart Association (NYHA) class II-IV, normal sinus rhythm with the QRS greater than or equal to 150ms with a left bundle branch block pattern (Yancy, et al., 2017). The American College of Cardiology, American Heart Association, and Heart Rhythm Society Guidelines recommend that a pacemaker should be followed-up every 3-12 months, and those with ICD's should be followed up every 3-6 months, with more frequent follow-ups as the battery approaches elective replacement (Wilkoff, et. al., 2008). While this is fairly frequent, this follow-up can occur remotely, termed remote monitoring, which can reduce the number of office visits a patient would need to make. In addition to battery monitoring, the pacemakers and ICD's can monitor arrhythmias, and lung fluid accumulation, or impedance monitoring (Burri & Senouf, 2009). Thoracic impedance monitoring provides the clinician with fluid thresholds within the chest wall of patients and can alert the provider to threshold crossings that indicate fluid overload, or acute decompensated heart failure (ADHF) (Blair, 2014). This review will demonstrate the state of evidence related to impedance monitoring on 30 day hospital readmission rates.

Impedance monitoring is not currently a guideline recommended therapy, however, there are extensive randomized controlled trials and cohort studies that support its use (Blair, 2014; Shochat, et al., 2017; Miyoshi, et al., 2017). Impedance monitoring frequency varies in clinics across the U.S.; however, more frequent monitoring could provide an opportunity for earlier

intervention in those who are experiencing fluid overload and prevent 30 day hospital readmission (Coller, 2013). The national average for 30 day HF hospital readmissions is 21.6% in the U.S. (CMS, 2017). Many hospitals aim to achieve a readmission rate that is less than or equal to the national average for reimbursement purposes from Medicare (AHA, 2017).

Problem Statement

HF is a chronic progressive disease that results in physical, emotional, and financial burdens for individuals and healthcare systems (Ivany & White, 2013). On average, 50% of patients with HF who have a HF hospital admission will be readmitted within 6-months, and nearly 21.6% are readmitted within 30 days (CMS, 2017). Increased impedance monitoring is not a routine surveillance to predict HF exacerbations despite evidence demonstrating reduced HF exacerbations and hospitalizations (Tung, et al., 2016). This integrative review helps inform providers regarding the most recent and best evidence available in incorporating thoracic impedance monitoring for the care of patients with heart failure. An integrative review is valuable to providers because it reviews what is known about a subject, examines the quality of the information, determines what additional information should be known, and provides a recommendation for next steps in research and practice (Holly, Salmond, & Saimbert, 2017).

Purpose & Significance of the Scholarly Project

The purpose of this project is to evaluate the literature related to impedance monitoring in patients with HF on 30 day hospital readmissions and quality of life. The principle aim is to provide a synthesis of the evidence and make a recommendation to cardiovascular clinicians.

Goals and Objectives

- Objective 1: To provide an integrative review of the literature related to the effectiveness of remote impedance monitoring in reducing 30 day HF hospital readmissions.

- Objective 2: To provide a recommendation for remote impedance monitoring for outpatient management of HF.

Clinical Questions

This integrative review will address the following clinical questions:

1. In patients with HFrEF who have an impedance monitoring device, does impedance monitoring reduce hospital 30 day readmission rates?
2. In patients with HFrEF who have an impedance monitoring device, does impedance monitoring impact quality of life?

Questions to support and maintain the focus of this review:

1. Are there any studies that evaluate the effect of impedance monitoring on quality of life?
2. Does increased impedance monitoring improve quality of life?
3. Is there a nursing theory that can be applied to thoracic impedance monitoring and heart failure care?
4. Does impedance monitoring identify early heart failure?
5. Does impedance monitoring decrease readmissions?

Methods

Integrative Review Framework: Whittemore & Knalf

The integrative review updated methodology by Whittemore and Knalf (2005) acted as the framework for this integrative review. This methodology distinguishes the integrative review from other review methods and allows for the combining of diverse methodologies, including empirical and theoretical, in the review (Whittemore & Knalf, 2005). Integrative reviews are the broadest type of research review and allow for the simultaneous inclusion of experimental and non-experimental research in order to fully encompass the information. This framework includes

the problem identification stage, data collection, literature search stage, data evaluation stage, data analysis stage, conclusion drawing and verification, and presentation stage. In addition to Whittemore and Knalf (2005), each manuscript was assigned a level of evidence (LOE) according to Melnyk's system of hierarchy (Appendix A). In addition to the integrative review methodology, Transitions Theory acted as the theoretical framework and is discussed in detail in this section.

Problem identification stage. The problem identification stage is the first step in the integrative review methodology. This stage is where a clear identification of the problem that the review is addressing occurs. This step provides focus and boundaries for the integrative review process (Whittemore & Knalf, 2005). This integrative review stems from the burden of heart failure on patients and healthcare systems. Its purpose is to analyze the literature related to a tool that can be used to manage heart failure and reduce the burden on both patients and healthcare systems. During the problem identification stage, data can be gathered from validated information sources to help guide the focus of the review. Hospital Compare's, a national Medicare database, 30 day readmission rates were used to support this integrative review's identified problem of higher readmission rates in patients with HF.

Literature search stage. The next phase of the Whittemore & Knalf (2005) framework is the literature search stage. When performing an integrative review well defined search strategies are used to ensure there is a complete and unbiased search. The methodology of the literature search process is shared in the results section of this paper, including search terms, databases used, and inclusion and exclusion criteria for determining relevant primary sources. This integrative review's search process was systematic in nature and included a discussion of

clinical guidelines, systematic reviews, clinical trials, cohort studies, literature reviews, and theory discussion.

Data evaluation stage. The data evaluation stage reviews the types of studies included in the paper in order to evaluate the overall quality of the search. This includes identification of clinical guidelines, systematic reviews, clinical trials, cohort studies and whether or not the primary sources used a mixed method or qualitative research, versus a quantitative research method (Whittemore & Knalf, 2005). The quality of the studies for this review are organized in an evidence table using Melnyk's hierarchy of evidence (Appendix A). The researcher also used specific selection criteria to help identify and structure the types of articles found.

Data analysis stage. In the data analysis stage the data in research reviews are ordered, coded, categorized, and summarized into a unified and integrated conclusion about the research problem. This enables the researcher to organize the evidence in an unbiased manner and provide innovative synthesis of the evidence. This stage encompasses data reduction, data display, and data comparison (Whittemore & Knalf, 2005). The articles for this integrative review are organized and discussed in a hierarchical format based on the level of evidence.

Data reduction. Data reduction is the determination of a classification system for managing data from diverse methodologies; for example, an integrative review includes information that is both qualitative and quantitative in nature. Primary sources are divided into subgroups according to some logical system to facilitate analysis (ex: qualitative/descriptive studies in one group). Sources can also be based on chronology, settings, and sample characteristics and are analyzed by topic. This organized technique enables the researcher to extract and code data into a manageable framework (Whittemore & Knalf, 2005). Predetermined/relevant data of each subgroup classification are extracted and complied into a

spreadsheet, which demonstrates succinct and organized literature, facilitating systematic comparison on issues, variables, and sample characteristics (Whittemore & Knalf, 2005). This integrative review utilized an evidence table organized into subgroups that classifies the level of evidence, type of study, and other characteristics.

***Data display*.** Displaying data is a way to show how the data from multiple varying types of studies shares results. This can be done using graphs, tables, and charts (Whittemore & Knalf, 2005). This integrative review utilized tables and figures to help display the literature from varying types of studies.

***Data comparison*.** Once data is organized and displayed the researcher can examine the displays for patterns, themes, or relationships. Concept mapping is another tool that can be used. Either tool used for data comparison helps to provide clarity for the empirical and/or theoretical components in the literature allowing support to emerge from early interpretive efforts (Whittemore & Knalf, 2005). This integrative review utilized an evidence table to organize the literature based on levels of evidence. The researcher found and displayed themes and commonalities in a flowchart.

Conclusion drawing and verification. After the data is compared, the researcher can then draw conclusions by isolating patterns and processes as well as commonalities and differences in the literature. These conclusions must be verified with the primary source for accuracy. In the event of conflicting evidence, the need for further research with subsequent research questions aimed at resolving the conflict is recommended. Important elements and conclusions are synthesized and integrated into a summation. It is recommended that the entire process be documented so that thoughts, analytical hunches, and alternate hypotheses are incorporated as possibly relating to the interpretation of the data (Whittemore & Knalf, 2005).

This integrative review utilized the evidence table and flowcharts to help draw a conclusion regarding a recommendation for providers related to impedance monitoring in patients with heart failure.

Presentation Stage. Lastly, the findings from the review are reported in explicit detail to provide a logical chain of evidence. Information that is already known is shared as well as the new information that the integrative review has added to the body of evidence and how it impacts or changes the existing general consensus (Whittemore & Knalf, 2005). This integrative review adds to the body of evidence by providing an extensive review of the literature and other concepts related to impedance monitoring and patients with HF.

Theoretical Framework: Transitions Theory

This review has adopted a theoretical framework for support. A theoretical framework is helpful for the review because it can be used to define and guide variables and the relationships between the variables. A theoretical framework can help with evaluation of outcomes and providing directions for care (Smith & Liehr, 2014). Transitions Theory was used as the theoretical framework for this review. Transitions Theory offers a guideline and framework for the various transitions in a patient's life. Also, this theory has an essential foundation within the nursing profession. A review of the literature was performed to identify supporting articles related to heart failure and Transitions Theory. Few articles were found and focused on palliative care, transitions prior to a cardiac procedure, and discharging from hospitals.

Afaf I. Melieis developed Transitions Theory through research with immigrants and the transitions they face when they enter the U.S. (Meleis, 2010). The purpose of the theory is to describe, explain, and predict experiences of people in types of transitions including health and illness, situational, developmental, and organizational (Smith & Liehr, 2014). Key theory

concepts describe the types and patterns of transitions an individual may go through. These transitions span the lifetime, from birth to death. Additionally, this theory identifies properties of transition experiences, such as an illness from which the individual is suffering. Transition conditions, patterns of response, and process and outcomes indicators are also concepts described in the theory. Nursing therapeutics are embedded throughout each transition. There is also a relationship between the concepts as the individual moves through life. This theory has been a popular nursing theory because it can be used in nursing practices for people across unique health-related transitions (Smith & Liehr, 2014).

Transitions Theory applies to patients with HF because they are they dealing with a serious health condition and learning how to manage this can be a difficult transition. The diagnosis itself is a transition and patients are sometimes faced with end-of life decisions. After diagnosis, there are markers of disease progression and transition, for example functional decline and increased dependence on others. This signals the need to transition their care to meet the patient's needs (Davidson et al. 2007). Nurses, at all levels, play a central role in the lives of patients as they journey through life's transitions. Nurses can aid in positive transitions by providing education, support, and/or direct care, thereby reducing disease and health risk. Additionally nurses enhance health and wellbeing and can assist those individuals as they move through transitions (Smith & Liehr, 2014). Impedance monitoring is a tool that can be used by clinicians and patients with HF to help them as they are dealing with their transition of managing a chronic disease (Blair, 2014). Patients with HF deal with a transition at diagnosis, from hospital to home, and throughout their disease process, which in many cases leads to subsequent admissions and end-of life. Transitions Theory will guide this review and careful attention will be paid to the transition from hospital to home and outpatient management.

Types and patterns. Transitions Theory has five concepts that will be related to this review. The first concept discusses the types and patterns of transitions an individual faces. During a lifetime an individual is faced with many transitions, including developmental, health and illness, situational, and organizational (Meleis, 2010). A diagnosis of HF is a major transition for an individual. Most people with this diagnosis are over the age of 65; however, older age does not make the adjustment easier. There are also individuals who are diagnosed with HF at a young age and undergo extensive treatment options such as a left-ventricular assist device and/or heart transplantation. A diagnosis of HF is characterized by a chronic progressive pattern of exacerbations and remissions evidenced by hospitalizations. This complex pattern is wearing on the patient, family members, and the healthcare team. This review acknowledges that a diagnosis of HF is a complex transition characterized by illness.

Properties of the transition. The second concept reviewed by Meleis (2010) includes the properties of the transition experience. These properties include awareness of the transition, engagement, changes and differences, time span, and critical points and events that take place during the transitions. Meleis (2010) notes that awareness of change does not mean a person is ready for the transition and lack of awareness does not mean that the transition has not begun. This directly relates to a diagnosis of HF, because the heart's ability to pump has already weakened before the patient is aware. Diagnosis is one of the most critical points during the disease process because the treatment plan is developed and prognosis is discussed. The time span of managing HF may last a few days, or may last years. It is critical to keep the patient and family members engaged and eager to participate in the care plan.

Transition conditions & process/outcomes indicators. Transition conditions is the next concept in Transitions Theory. There are many conditions that influence the way a person moves

through a transition. Conditions can facilitate or inhibit the transition process and outcomes. These conditions may be personal or community and societal (Meleis, 2000). The family unit is a major condition that impacts how a person moves through a transition. The support, or lack of support, from a family member or caregiver can positively or negatively impact how a person moves through the diagnosis and management of HF. These conditions influence the next phase of the concepts, which include patterns of response-process and outcomes indicators. Process indicators lead the patient toward health or vulnerability and risk. Outcome indicators are used to determine if the transition is healthy or not (Meleis, 2000). This review seeks to identify positive conditions surrounding patients with HFrEF by evaluating impedance monitoring on 30 day hospital readmissions and quality of life.

Nursing therapeutics. Lastly, nursing therapeutics is the final concept described by Meleis (2010) in Transitions Theory. Nurses are able to assess a patient's readiness to accept the transition (Weis, et al., 2007). Nurses are part of a multidisciplinary effort and comprehensive treatment plan that seeks to help the patient and understand the needs of the patient. Nurses help prepare the patient through each stage of the transition and educate during critical points and events to promote the best outcome. Nurses also help people to understand the new role they may play as a result of their illness. These concepts are interrelated and adaptable, just as transitions flow and move over time. Transitions cause a change in identity, roles, relationships, and patterns of behavior. For example, children may have to become the caregiver for their elderly parent with HFrEF (Smith & Liehr, 2014).

Christian worldview. Ecclesiastes is a book in the Bible written by King Solomon and inspired by God. He describes the transitions that occur in life. He wrote that there is a time to be born, and a time to die; a time to heal, and a time to break down. Looking at life from a Biblical

perspective gives meaning to life's transitions. Solomon states there is a season and a time for everything under heaven. Jeremiah 29:11, is another Scripture passage that describes how God has a plan for each of us, and His plan is good. Applying the theory of transitions to this review as a theoretical framework incorporates the nursing perspective and its impact on patient care.

Evaluation Methods

This integrative review was evaluated by the author and chair on a continual basis to ensure that the evolving document upheld exactitude and met the requirements of the Doctor of Nursing Practice program at Liberty University.

Search Strategy

The search strategy to identify the best evidence related to impedance monitoring to reduce readmissions for patients with heart failure with reduced ejection fraction (HFrEF) included a search of the Cochrane Library, CINAHL, and PUBMED. Keywords and phrases used for the search included impedance monitoring, heart failure, readmission rates, costs, and quality of life. Supporting questions were also used to help narrow the articles. No limits were placed on type of article or publication date. The search was limited to the English language and available free full text. These searches produced 196 hits. CINAHL produced 19 hits, Cochrane produced 74 hits, and PUBMED produced 103 hits.

Study Identification

The researcher narrowed the search by publication date (2012-2017), study design, (clinical practice guideline, systematic review, controlled trial, cohort study, literature review, and theory) and available full text, which yielded 25 studies for review. Abstracts of the 25 articles were reviewed for selection criteria. If any of the selection criteria were not indicated as a primary component, then the study was excluded from this systematic review. If the abstract

did not provide adequate information to determine selection criteria, the full text publication was reviewed. Studies that were appraised and included in identified systematic reviews were not individually appraised or discussed in this systematic review. A search of the National Guidelines Clearinghouse was conducted for professional guidelines pertaining to heart failure disease management to inform this review. After excluding articles that did not meet the selection criteria there were 14 articles included in this review and critical appraisal.

Selection Criteria

Population. The focus of this review was patients with HFrEF with impedance-monitoring capability in their pacemaker device.

Intervention. The intervention of interest was impedance monitoring in patients with HFrEF.

Outcome. The principle outcomes of interest were hospital readmission rates, quality of life, and theory application.

Study Design. Articles were included if they were classified as a clinical practice guideline, systematic review, controlled trial, cohort study, literature review, or theory discussion.

Methods for Quality Assessment

A single reviewer critically appraised the quality of each manuscript. Clinical practice guidelines were appraised according to the Appraisal of Guidelines Research & Evaluation (AGREE, 2006). Each manuscript was assigned a level of evidence (LOE) according to Melnyk's system of hierarchy (Appendix A).

Inclusion	Exclusion
Publications from 2012-2018	Publications prior to 2012
Subjects greater than 18 years of age	Subjects less than 18 years of age
Study design	Non research articles
English language	Language other than English
Full-text articles	Abstract only articles

Table 1. Inclusion and Exclusion Criteria

Critical Appraisal

Clinical Practice Guidelines

The 2017 focused update guideline for the management of HF does not address impedance monitoring as a tool for the identification and management of HF (Yancy et al., 2017). While this is not a current recommendation in the guidelines for HF and there is no mention of impedance monitoring in the report, the Heart Rhythm Society (HRS) and European Heart Rhythm Association (EHRA) have developed an expert consensus document in collaboration with the American Heart Failure Society and other professional organizations related to the techniques, indications, personnel, frequency, and ethical considerations of monitoring cardiovascular implantable electronic devices. This consensus mentions impedance monitoring in addition to rhythm monitoring, pacing, defibrillation, and battery monitoring (Wilkoff, 2008). It is recommended that a minimum frequency for in person or remote monitoring occur every 3-12 months, or more frequently if the device is a defibrillator. These recommendations are more extensive and discuss monitoring (battery, rhythm, leads, and thoracic impedance) from implantation through battery depletion. This document also discusses

the wide range of variety in the frequency of remote monitoring devices at a worldwide level and provided some basic recommendations for device monitoring. Disease-related monitoring, and specifically thoracic impedance monitoring as part of disease management in HF, is discussed as a goal for implantable devices (Wilkoff, 2008).

Systematic Reviews

One systematic review was discovered that related to the study topic. Blair (2014) synthesized 24 randomized controlled trials that were performed to determine if device diagnostics could be used to identify HF exacerbations in the clinical setting. The purpose of this review was to determine if this early identification of HF can reduce hospitalizations with reduction of readmissions being its principle objective. The 24 studies were obtained using the databases of CINHAHL, MEDLINE, PubMed, and ClinicalTrials.gov. These studies were divided into two categories based on the primary objectives examined (Blair, 2014).

First, the efficacy and prognostic value of device diagnostic data was evaluated and second the clinical feasibility of device diagnostic data and its impact on patient outcomes was evaluated. This systematic review found that device data is capable of predicting HF exacerbations and also preventing hospitalizations. A strong correlation between cardiac biomarkers and hemodynamic measures was also discovered. The findings from this review indicate the ability for device diagnostics to assist clinicians to predict acute decompensated HF (ADHF) much earlier than other indicators, such as patient reported symptoms (Blair, 2014). The objective measures available with device diagnostics enables clinicians to be better informed and initiate communication with the patient rather than waiting for symptoms to be triggered. This allows for better clinical decision making because better and more accurate information is available to the clinician (Blair, 2014). This systematic review supports the importance of

utilizing device diagnostics to identify HF exacerbations and prevent hospitalizations. A study limitation that was shared by the author is that a bias exists towards Medtronic because the literature available on this topic was primarily from studies using Medtronic devices (Blair, 2014).

Clinical Trials

Multiple clinical trials have been performed to evaluate the impact of impedance monitoring on patients with HF and have shown a reduced rate of hospitalizations as well as increased survival. The lung impedance monitoring in treatment of chronic heart failure (LIMIT-CHF) trial was an evidence-based European study published in 2016 and evaluated the impact of alerts on preventing HF hospitalizations for those patients who had device data and alert capability (Domenichini, et al., 2016). The purpose of this trial was to evaluate the impact of alerts on preventing HF hospitalizations with the primary objective being to reduce readmissions. This was a randomized controlled trial and patients with chronic HF with OptiVol or CorVue capable implantable cardioverter-defibrillators were randomized to either the active group (IIM alarm turned on and diuretic dose increased by 50% for 1 week in the event of an alarm sounding) or the control group (alarm turned off). The primary endpoint of the trial was HF hospitalizations. Eighty patients were included in the study and divided into two groups: active group (41 patients) and control group (39 patients) however, 71 patients reached the one-year follow-up. There was a total of 11 HF hospitalizations in the active group vs. 6 in the control group without a significant difference in the number of episodes for each patient (Domenichini, et al., 2016). A decreased trend in MLWHF scores was found in the active group compared to an increased trend in the control group. This indicates an improved quality of life in the active group versus a reduced quality of life in the control group. While the study results did not show a

reduction in emergency HF treatment, there was a positive impact on quality of life. A limitation shared is that there were a relatively high amount of IIM alerts that were not detected and consequently were not treated per the protocol. This may have reduced the potential benefit of alert guided treatment (Domenichini, et. al., 2016).

The MOMOTARO (Monitoring and Management of OptiVol Alert to Reduce Heart Failure Hospitalizations) is a trial that was performed in Japan. This study's purpose was to review a new algorithm that can be used to calculate impedance. The study's objective was to reduce HF hospitalizations. The study consisted of 195 patients who had been implanted with a high-energy device and assessed the potential that fluid index could predict fluid accumulation and ADHF (Miyoshi, et al., 2017). The algorithm modification was then used to reduce the number of false-positive threshold crossings for HF and to more accurately diagnose actual fluid accumulation in patients at baseline and at an alert. During the study there were 154 primary HF events that were detected with the previous algorithm and there was no significant difference of the BNP between the baseline and alert. Using the modified algorithm, only 37 reached the threshold and the log BNP was significantly higher in these 37 events compared with the baseline value (Miyoshi, et al., 2017). This study supports the need to assess the fluid index in patients with devices and use it to assist in predicting fluid accumulation. Study strengths were that this was a randomized controlled trial with findings that support the study topic. Limitations include that this was a simulation rather than a prospective clinical study and raw data for patients with HF hospitalizations without threshold crossing events was not retained as a control and both would be recommended. Many factors can impact fluid retention in the chest wall including infection, pneumonia, and anemia and this new algorithm cannot detect between these other pathological conditions (Miyoshi, et al., 2017).

The IMPEDANCE-HF trial was a randomized controlled trial that consisted of 256 patients from 2 medical centers with chronic HF and ejection fraction (EF) <35% with New York Heart Association Class II-IV symptoms who were admitted for ADHF within 12 months. The purpose of this trial was to measure the degree of pulmonary congestion with non-invasive impedance and its objective was to reduce HF hospitalizations (Shochat, et al., 2016). The non-invasive impedance monitoring means that it was not an implanted device, which is the traditional method for impedance monitoring. This new technology uses an electromagnetic field to externally measure thoracic impedance. The 256 patients were randomized into the control group and the therapy group. The therapy group had noninvasive lung impedance measures performed monthly (every 30-days) and were followed for at least 12 months. Patients were blind to their assignment group. The primary endpoint was AHF hospitalizations and the secondary endpoint was all-cause hospitalizations and mortality. There were 67 (monitored group) v. 158 (control group) AHF hospitalizations during the first year, and 211 v. 386 AHF hospitalizations during the entire follow-up among the monitored patients (Shochat et al., 2016). During the follow-up there were 42 and 59 deaths, 13 and 31 resulting from HF. IMPEDANCE-HF trial results showed that lung impedance guided treatment reduces hospitalizations for heart failure and decreases HF-related mortality. These results validate the concept that lung impedance preemptive treatment reduces hospitalizations and incidence of HF, as well as CV and all-cause mortality (Shochat et al., 2016). This study added tremendous evidence that early detection of hemodynamic changes enables clinicians to intervene early and in the outpatient environment (HFSA, 2016). The trial was extended to include a one-year follow-up sought to demonstrate the impact of impedance monitoring on survival (Shochat et al., 2016). This follow-up was the first lung impedance trial that demonstrated this type of guided pre-emptive therapy

of worsening pulmonary congestion prevents HF hospitalizations, both HF and all-cause. This study also demonstrated that all-cause, cardiovascular and HF mortality was reduced. The study measured lung impedance with a new non-invasive high-sensitive device and supports the use of monthly impedance monitoring in patients with HF (Shochat et al., 2016). Strengths of the IMPEDANCE-HF study include that it offers cardiovascular clinicians insight into several clinical questions around the management of HF. First, it addresses that impedance monitoring can identify the degree of pulmonary congestion. Second, it addresses that pre-emptive monitoring, specifically every 30-days (more frequent than the current expert consensus recommendation) does reduce HF hospitalizations. Lastly, it addresses that impedance monitoring reduces all-cause and HF mortality. Limitations to this study include that the impedance monitoring device used was a new technological non-invasive tool, not specifically named in the study, and this technology is not as prevalent as traditional pacemaker impedance technologies. Also, this was a limited trial at one hospital site. A larger study across multiple centers would further clarify the benefits of impedance monitoring.

Cohort Studies

The researcher found multiple cohort studies in the literature that evaluated the use of impedance monitoring in the management of patients with HF. A prospective observational cohort study examined the correlation between pulmonary artery pressure and thoracic impedance and daily monitoring. The purpose of this study was to observe the impact of CardioMems, a small device implanted into the pulmonary artery, and measure pulmonary artery pressures (PAP) on thoracic impedance (Perego, et al., 2017). This was a study of 10 patients with HFrEF who had previously been implanted with an ICS capable of measuring thoracic impedance. Those patients were then implanted with CardioMems and both impedance and PAP

were remotely monitored daily. Investigators were blind to the PAPs for the first three months, then the PAP level was used to guide therapy. The study found that there is a direct correlation between left ventricle filling pressures and lung water content, however, there is a limited value in predicting episodes of thoracic impedance decrease (Perego et al., 2017). However, thoracic impedance decrease and PAP elevation precede ADHF. This study supports the need to perform impedance monitoring in patients who have the device capability. Study limitations include the small sample size and that the study participants were coincidentally all males, so gender related differences could not be excluded. Variations of thoracic impedance and PAPs were defined if they lasted greater than 7 days, so this definition may have influenced the study results (Perego et al., 2017).

The next study is a single-center prospective cohort study seeking to evaluate device monitoring in HF patients with a cardiac resynchronization therapy (CRT) device. Eighty patients were prospectively enrolled when they were implanted with biventricular defibrillators that had impedance monitoring capability (Forleo et al., 2013). Clinical heart failure status and impedance data were assessed during follow-up and if patients presented with an alert or heart failure deterioration. During follow-up there were 56 events of fluid index alerts identified in 29 patients. Confirmed ADHF occurred in 23 out of the 29 patients. Confirmed ADHF resulted in 14 hospitalizations and 7 of the 14 were preceded by an alert. False positives occurred in 23 of the 80 patients. False negatives are the primary study limitation with small sample size being another limitation. In summary, of the 56 fluid alerts, half were confirmed cases of heart failure. This study supports that impedance monitoring programs are feasible and can help to predict a HF exacerbation (Forleo et al., 2013).

A subsequent cohort study sought to determine the effectiveness of impedance monitoring in heart failure patients with implanted cardiac defibrillators. The purpose of this study was to determine the effectiveness of impedance monitoring on heart failure and to assess patient's perceptions of self-care. The researcher recruited 25 participants at a large private cardiology practice during an ICD interrogation if an impedance alert was triggered. After 30 days a chart review was performed to assess if any intervention occurred in direct relation to the patient's heart failure. The researcher administered the Self-Care of Heart Failure Index test as a pre and posttest to all patients to assess management, maintenance, and confidence in relation to their self-care habits (Franchuk, 2017). Twenty-one study participants were male and 4 were female with the mean age of 69.5 years. The primary study result showed that patients confidence increased related to management of symptoms due to the surveillance of impedance monitoring. This article approached impedance monitoring from a different perspective and gave insight into how this type of device monitoring can influence patients' abilities to perform self-care. Study limitations shared by the author include that data collection only occurred at one office. Time constraint was also a study limitation because this study was performed during an academic year. Attrition rates were high for the phone recruitment resulting in a smaller sample size (Franchuk, 2017).

Shapiro, Bires, Waterstram-Rich, and Cline (2017) performed a retrospective chart review study to evaluate clinical outcomes for patients with class III heart failure. The study objective was that patients with Class III chronic HF who received interventions in the form of an implanted CorVue ICD and home health care would have fewer 30 day readmissions than patients who only received home care. The principle outcome of interest was to see if patients with CorVue ICD have lower 30-day readmission rates than patients without the device (Shapiro,

et al., 2017). One hundred and twenty patients were divided into a study group and a control group with 60 patients in each group. The researcher analyzed thirty-day readmission and mortality rates in each group. No patients with CorVue experienced a 30 day readmission. In contrast, 14 of 60 patients in the control group did experience a 30 day readmission (Shapiro, et al., 2017). This particular study had a 90 day time period with a small sample size therefore validity cannot be certain or results generalized. More studies are needed to determine which interventions have the greatest financial impact as well as patient outcomes improvement (Shapiro, et al., 2017).

The Detect Fluid Early from Intrathoracic Impedance Monitoring (DEFEAT-PE) is a prospective multicenter study that used impedance monitoring to detect pulmonary congestion (Heist et al., 2014). This study analyzed different intrathoracic vectors and their ability to predict ADHF. One hundred sixty-two patients were enrolled, 80 participants had ICDs and 82 had CRT-Ds. All participants had greater than or equal to one event of pulmonary congestion. An alternative algorithm was used to detect pulmonary congestion and resulted in a sensitivity of 21.6% and a false-positive rate of 0.9% per patient year. The DEFEAT-PE algorithms resulted in low sensitivity for the prediction of heart failure events; however, they were able to achieve an acceptably low false-positive rate. The Federal Drug Administration ultimately approved this algorithm.

Results & Summary of Evidence

In Patients with HFrEF Who Have an Impedance-monitoring Device, Does Impedance Monitoring Reduce Hospital 30 day Readmission Rates?

While impedance monitoring is not a recommendation for care in the guidelines for patients with HF (Yancy et al. 2017), there is sufficient evidence in the literature that support its

use. The evidence supports that impedance monitoring identifies ADHF. Impedance monitoring can be a useful tool to predict fluid accumulation in patients with HF prior to symptom onset and can allow clinicians to intervene quickly with outpatient therapies (Franchuk, 2017). The studies provide evidence that its use can reduce hospital readmissions and mortality (Blair, 2014; Miyoshi et al., 2017; Shochat, et al. 2016). The literature supports that implementation of impedance monitoring programs in patients with HF can impact hospital readmissions and mortality rates. These outcomes are beneficial for patients and hospital networks as patient outcomes are often directly linked with financial incentives from insurance companies. A single systematic review, three clinical trials (IMPEDANCE-HF), and five cohort studies support the use of impedance monitoring to identify early ADHF (Blair, 2014; Domenichini et al., 2016; Miyoshi et al., 2017; Shochat et al., 2016; Shochat et al., 2016; Forleo et al., 2013; Heist et al., 2014; Perego, et al., 2017; Franchuk, 2017; Shapiro, et al., 2017).

Gaps identified include limited discussion on increased (more frequent than 3-12 month monitoring) and 30 day readmission rates. This researcher found one study that explored this supporting clinical question (Shochat et al., 2016) using a new technology. This study did find that 30 day monitoring reduces hospital readmissions (Shochat, et al., 2016). More studies are needed to support their study findings.

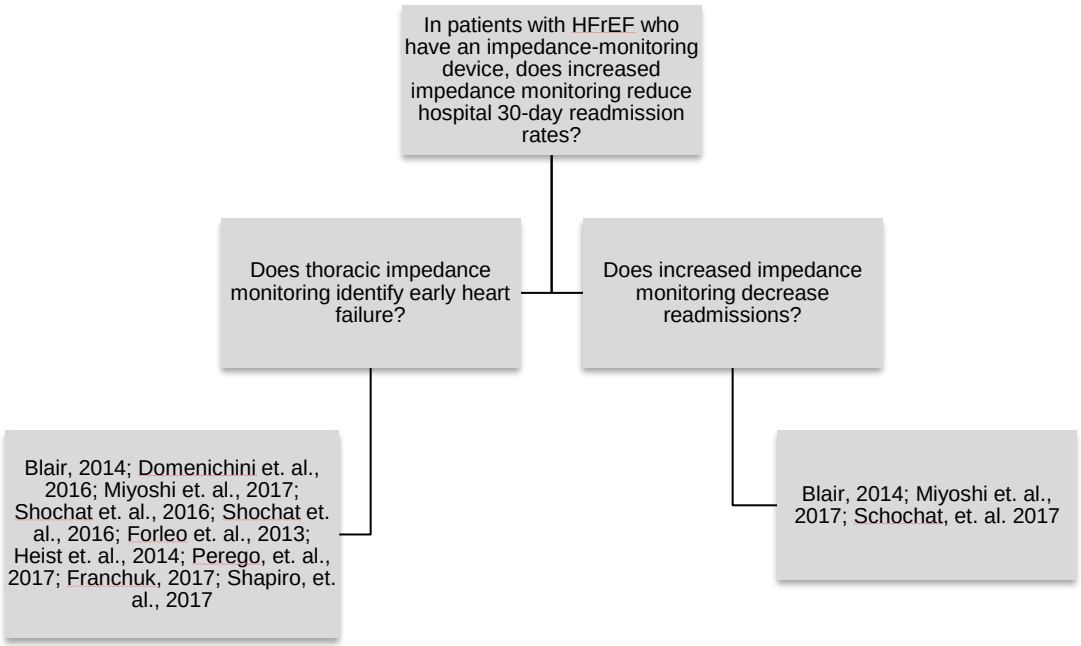

Figure 1. Impact of Impedance Monitoring on Readmissions.

In Patients with HFrEF Who Have an Impedance-monitoring Device, Does Impedance Monitoring Impact Quality of Life?

Impedance monitoring has the ability to impact the quality of life for patients with heart failure. The LIMIT-CHF Trial specifically analyzed quality of life in patients with HF who underwent impedance monitoring and reported that there was an improvement in quality of life (Domenichini e. al., 2016). The other clinical trials and cohort studies did not discuss quality of life as an outcome of interest.

The HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable devices discussed that a goal of implanted cardiovascular devices with monitoring capability is to optimize quality of life; this encompasses thoracic impedance monitoring. However, no further discussion was provided on whether or not quality of life is an influencing factor on thoracic impedance recommendations (Wilkoff, 2008). Patients, however, expressed that this

type of monitoring helped them to identify positive behaviors and lifestyle modifications that can reduce cardiovascular risk (Franchuck, 2017; He & MacGregor, 2011).

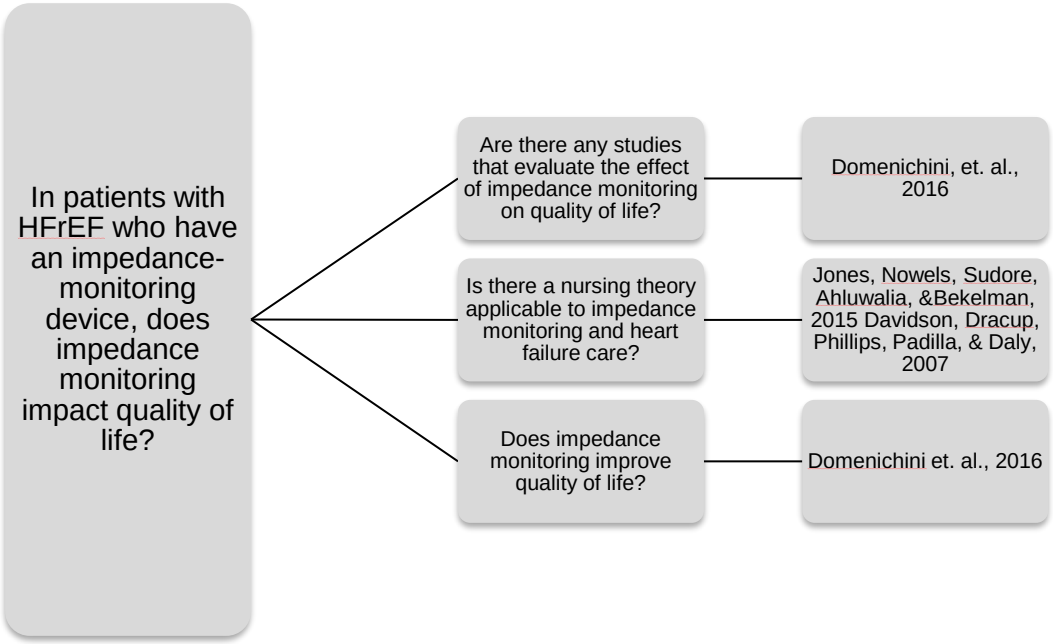

Figure 2. Impact of Impedance Monitoring on Quality of Life.

Additional Analysis

A common theme throughout each article regardless of their study design was that there is a transition occurring in the patient's health. This transition is marked by a heart failure diagnosis and/or hospitalized exacerbation and continues with discharge to home and management of the chronic illness. This theme led the reviewer to explore nursing theories around transitions and Transitions Theory was found to be very applicable to patients with heart failure.

Limitations

Limitations shared in the literature included that there may be a bias towards Medtronic in the results of clinical trials because many clinical trials used Medtronic devices.

Discussion

Implications for Research

Continued research is recommended to further solidify the use of impedance monitoring in the management of heart failure. This review highlights the current evidence related to impedance monitoring and early identification of HF, interventions used to manage HF, and impact on quality of life. More information is needed to see if more frequent impedance monitoring reduces 30 day hospital readmissions.

Implications for Practice

The significance of this review can greatly impact patients with HF and how they perceive their quality of life. The potential to predict a HF exacerbation enables the HF team to intervene prior to decompensation. Patients with HF often suffer from depression and struggle with the reality of living with a chronic disease (Herr et al., 2017). Quality of life is a major outcome in patients with HF and the ability to improve quality of life through impedance monitoring is impactful. At the micro level, or patient and clinician level, this can help to improve the patient and provider relationship. In addition to an improved relationship, the patient will have a better quality of life evidenced by a decrease in exacerbations requiring hospitalizations. At the organizational level, or the mesa level, the number of patients that are prevented from hospital admission can greatly impact the financial implications. Readmissions are costly for the patient and the organization because readmissions are associated with payment penalties. With a reduction in readmissions the penalties will decrease and enable the organization to save financially. Nationally this may help patients across the country that struggle with HF and as technology advances there may further innovations created enabling patients to review their threshold levels in real time and help them to make better decisions related to self-care (Forleo et al., 2013).

The profession of nursing can utilize impedance monitoring as a patient education tool and as an assessment tool. Home health nurses and other nurses can utilize the data to help the patient identify when fluid is developing so that changes can be made in their lifestyle or medications (Shapiro, 2017). Nurses across the country are caring for patients with HF; nearly every nurse has encountered a patient with this diagnosis. This review and other scholarly projects help to elevate the profession of nursing amongst the healthcare community. Subsequent scholarly work related to impedance monitoring can continue as new technologies and devices are being developed.

DNP Essentials

Essential I: scientific underpinnings for practice

The DNP Essentials highlight the preparation of the doctorate prepared nurse and the many avenues of healthcare that the nursing profession embodies. The first essential is the Scientific Underpinnings for Practice, which reflects the complexity of practice at the doctoral level and the rich heritage that is the conceptual foundation of nursing. This integrative review reflects this essential by integrating nursing science with knowledge that is biophysical, psychosocial, analytical, and organizational. This review used science-based theories and concepts to determine the nature and significance of health and health care delivery, described the actions and advanced strategies to enhance the care of heart failure patients, and evaluated the outcomes of the literature (AACN, 2017).

Essential III: clinical scholarship and analytical methods for evidence-based practice

This review reflects the hallmark of the doctoral education by providing a detailed analytical scholarship review related to the care of patients with HF. This review incorporates

this DNP Essential by investigating and synthesizing evidence across disciplines and types of research to help solve health care problems and improve health outcomes. This review used analytical methods to critically appraise the literature to inform providers and institutions regarding the use of impedance monitoring technologies in the care of patients with HF (AACN, 2017). An integrative review appraises and combines available evidence, including theory and other information. This review method incorporates diverse methodologies to capture circumstances, processes, and individual elements of the topic under study (Whittemore & Knafl, 2005). This type of review takes traditional review methods further and provides a broader focus (Holly, Salmond, & Saimbert, 2017) evidencing the exactitude of the DNP.

Essential IV: information systems/technology and patient care technology for the improvement and transformation of health care

This essential distinguishes the DNP graduate's ability to use information systems and technology to support and improve patient care and healthcare systems and provide leadership within healthcare systems. This review assists providers in the use of information systems/technology to evaluate programs of care, outcomes of care and care systems. By performing this integrative review, healthcare providers will be better informed about the impact of thoracic impedance technologies on 30 day hospital readmissions and quality of life for patients with heart failure (ACCN, 2017).

Conclusion

In closing, managing patients with HF is a multidisciplinary effort with the patient being the most important member of the healthcare team. Diagnosis of HF is often a concerning diagnosis for patients and family members. HF it is very difficult to medically and self-manage and is characterized by exacerbations, and hospitalizations. Many patients with HF are on an

end-of-life trajectory, as HF is one of the nation's leading causes of death. One way to help to manage symptoms and decrease hospitalizations is to utilize impedance-monitoring capabilities through device technology. This review adds to the body of evidence for cardiovascular clinicians, thus improving the health of those who suffer with HF. Not only can impedance monitoring be a tool to reduce readmissions, but it can also be a tool evaluate quality of life, the patient's ability to perform self-care, and identify when end of life discussions may need to take place. Impedance monitoring can be a diverse tool for the management of this chronic and progressive disease. The updated methodology by Whittemore and Knalf (2005) and Transitions Theory strengthen this integrative review. This review also is in conjunction with the DNP Essentials and seeks to evidence the scholarship and evidence-based values of the DNP. By incorporating the findings from this review the hope is that cardiovascular clinicians are better empowered to manage HF and help patients with quality of life.

References

AACN. (2006). AACN talking points in response to the AMA's resolution 211. *Journal of Professional Nursing, 22*(5), 265.

AACN, American Association of Colleges of Nursing. (2017). DNP Essentials. Retrieved from http://www.aacnnursing.org/DNP/DNP-Essentials

AHA, American Heart Association. (2017). Get with the guidelines heart failure. Retrieved from https://www.heart.org/HEARTORG/Professional/GetWithTheGuidelines/GetWithTheGuidelines-HF/Get-With-The-Guidelines-Heart-Failure-Home-Page_UCM_306087_SubHomePage.jsp

AHA, American Heart Association. (2017). Heart failure projected to increase dramatically, according to new statistics. Retrieved from https://news.heart.org/heart-failure-projected-to-increase-dramatically-according-to-new-statistics/

AHA, American Heart Association. (2017). Trendwatch: Rethinking the hospital readmissions reduction program. Retrieved from https://www.aha.org/guidesreports/2015-03-19-trendwatch-rethinking-hospital-readmissions-reduction-program

Blair, T. L. (2014). Device diagnostics and early identification of acute decompensated heart failure: a systematic review. *The Journal of Cardiovascular Nursing, 29*(1), 68-81.

Brasca, F. A., Franzetti, J., Rella, V., Malfatto, G., Brambilla, R., Facchini, M., & Perego, G. B. (2017). Retrospective application of program to access and review trending information and evaluate correlation to symptoms in patients with heart failure criteria for the remote management of patients with cardiac resynchronisation therapy. *Journal Of Telemedicine & Telecare, 23*(4), 470-475.

Buckley, L. F., Carter, D. M., Matta, L., Cheng, J. W., Stevens, C., Belenkiy, R. M., & Desai,

A. S. (2016). Intravenous Diuretic Therapy for the Management of Heart Failure and Volume Overload in a Multidisciplinary Outpatient Unit. *JACC. Heart Failure, 4*(1), 1-8.

Burri, H. & Senouf, D. (2009). Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators. *Europace, 11*(6), 701-709.

CDC, Centers for Disease Control. (2018). Bundled payments for care improvement (BPCI) Initiative: General information.

CDC, Centers for Disease Control and Prevention. (2016). Heart failure fact sheet. Retrieved from http://www.cdc.gov/dhdsp/data_statistics/fact_sheets/fs_heart_failure.htm

Center, Deborah. (2011). Safe Handoffs Improve Transitions of Care to Home Care. *Colorado Nurse*, 9-11.

CMS, Centers for Medicare & Medicaid Services. (2017). Hospital compare. Retrieved from https://www.medicare.gov/hospitalcompare/profile.html#vwgrph=1&profTab=4&ID=490021&loc=24501&lat=37.3594913&lng=-79.1209829&name=CENTRA%20%20HEALTH%2C%20INC&Distn=5.7

Coller, J.M., Campbell, D.J., Krum, H., Prior, D.L. (2013). Early identification of asymptomatic subjects at increased risk of heart failure and cardiovascular events: Progress and future directions. *Heart, Lung and Circulation, 22*(3), 171-178.

Davidson, P.M., Dracup, K., Phillips, J., Padilla, G., & Daly, J. (2007). Maintaining hope in transition: A theoretical framework to guide interventions for people with heart failure. *Journal of Cardiovascular Nursing, 22*(1), 58-64.

Domenichini, G., Rahneva, T., Diab, I. G., Dhillon, O. S., Campbell, N. G., Finlay, M., & Finlay, M. C. (2016). The lung impedance monitoring in treatment of chronic heart

failure (the LIMIT-CHF study). *EP: Europace, 18*(3), 428-435.

Feltner, C., Jones, C. D., Cené, C. W., Zheng, Z., Sueta, C. A., Coker-Schwimmer, E. L., & Jonas, D. E. (2014). Transitional care interventions to prevent readmissions for persons with heart failure: A systematic review and meta-analysis. *Annals of Internal Medicine, 160*(11), 774-784. doi:10.7326/M14-0083

Forleo, G. B., Panattoni, G., Schirripa, V., Papavasileiou, L. P., Della Rocca, D. G., Politano, A., & Romeo, F. (2013). Device monitoring of heart failure in cardiac resynchronization therapy device recipients: A single-center experience with a novel multivector impedance monitoring system. *Journal of Cardiovascular Medicine, 14* (10), 726-732.

Franchuk, A. (2017). Determining the effectiveness of impedance monitoring in heart failure patients with implanted cardiac defibrillators. *EP Lab Digest, 17*(9).

He, F.J. & MacGregor, G.A. (2011). Salt reduction lowers cardiovascular risk: Meta-analysis of outcome trials. *The Lancet, 378*, 380-381.

Heist, E. K., Herre, J. M., Binkley, P. F., Van Bakel, A. B., Porterfield, J. G., Porterfield, L. M., & Pavri, B. B. (2014). Analysis of different device-based intrathoracic impedance vectors for detection of heart failure events (from the Detect Fluid Early from Intrathoracic Impedance Monitoring Study). *American Journal of Cardiology, 114*(8), 1249-1256.

Herr, J. K., Salyer, J., Lyon, D. E., Goodloe, L., Schubert, C., & Clement, D. G. (2014). Heart failure symptom relationships: A systematic review. *Journal Of Cardiovascular Nursing*, *29*(5), 416-422.

HFSA, Heart Failure Society of America. (2016). The non-invasive lung impedance-guided

preemptive treatment in patients with chronic heart failure (IMPEDANCE-HF) trial. Retrieved from http://www.hfsa.org/impedance-trial/

Holly, C., Salmond, S., & Saimbert, M. (2017). *Comprehensive systematic review for advanced practice nursing* (Second ed.). New York: Springer Publishing Company, LLC.

Ivany, E., & While, A. (2013). Understanding the palliative care needs of heart failure patients. *British Journal of Community Nursing*, *18*(9), 441-445.

Jones, J., Nowels, C.T., Sudore, R., Ahluwalia, S., Bekelman, D.B. (2015). The future as a series of transitions: qualitative study of heart failure patients and their informal caregivers. *Journal of General Internal Medicine, 30*(2), 176-182.

Lillyman, S., & Farquharson, N. (2013). Self-care management education models in primary care. *British Journal of Community Nursing*, *18*(11), 556-560.

Mateo, M.A. & Foreman, M.D. (2014). *Research for advanced practice nurses* (Second ed.). New York, NY: Springer Publishing Company, LLC.

Marques de Sousa, M., dos Santos Oliveira, J., Oliveira Soares, M. G., Amorim de Araújo, A., & dos Santos Oliveira, S. H. (2017). Quality of life of patients with heart failure: integrative review. *Journal of Nursing UFPE / Revista De Enfermagem UFPE, 11*(3), 1289-1287.

Mbakwem, A., Aina, F., & Amadi, C. (2016). Expert opinion-depression in patients with heart failure: Is enough being done? *Cardiac Failure Review*, *2*(2), 110-112.

Meleis, A.I., Sawyer, L.M., Im, E.O., Messias Hilfinger, D.K., Schumacher, K. (2000). Experiencing transitions: An emerging middle-range theory. *Advances in Nursing Science, 23*(1), 12-18.

Meleis, A.I. (2010). *Transitions theory: Middle-range and situation-specific theories in nursing*

research and practice. New York, NY: Springer Publishing Company, LLC.

Mirkin, K. A., Enomoto, L. M., Caputo, G. M., & Hollenbeak, C. S. (2017). Risk factors for 30-day readmission in patients with congestive heart failure. *Heart & Lung, 46*(5), 357-362.

Moran, K., Burson, R., Conrad, D. (2017). *The doctor of nursing practice scholarly project: A framework for success* (2nd ed.). Burlington, MA: Jones & Bartlett Learning, LLC.

Murtaugh, C. M., Deb, P., Zhu, C., Peng, T. R., Barrón, Y., Shah, S., & Siu, A. L. (2017). Reducing readmissions among heart failure patients discharged to home health care: Effectiveness of early and intensive nursing services and early physician follow-up. *Health Services Research, 52*(4), 1445-1472.

Nadruz, W., West, E., Santos, M., Skali, H., Groarke, J. D., Forman, D. E., & Shah, A. M. (2016). Heart Failure and Mid-Range Ejection Fraction: Implications of Recovered Ejection Fraction for Exercise Tolerance and Outcomes. *Circulation. Heart Failure*, *9*(4).

Perego, G. B., Oldani, M., Pellegrini, D., Brasca, F. A., Malfatto, G., Villani, A., & Parati, G. (2017). Correlation between pulmonary artery pressure and thoracic impedance: Insights from daily monitoring through an implanted device in chronic heart failure. *International Journal of Cardiology*, *245*196-200.

Pietri, G., Van Ganse, E., Ferrer, M., Garin, O., Wiklund, I. (2004). Minnesota living with heart failure questionnaire user manual. Retrieved from http://178.23.156.107:8085/Instruments_files/USERS/mlhf.pdf

Rector, T.S. (2017). FDA medical device development tool (MDDT) qualification package for the Minnesota living with heart failure questionnaire (MLWHFQ). Retrieved from https://djhurij4nde4r.cloudfront.net/attachments/files/000/000/483/original/MLHFQ_FDA_Medical_Device_Development_Tool_(MDDT)_Qualification_Package.pdf?15161139

48

Riley, J.P. & Masters, J. (2016). Practical multidisciplinary approaches to heart failure management for improved patient outcome. *European Heart Journal Supplements, 18*(G,1), G43-G52.

Rizzo, E. (2013). 6 stats on the cost of readmission for CMS-tracked conditions. Retrieved from https://www.beckershospitalreview.com/quality/6-stats-on-the-cost-of-readmission-for-cms-tracked-conditions.html

Savarese, G. & Lund, L.H. (2017). Global public health burden of heart failure. *Cardiac Failure Review, 3*(1), 7-11.

Shochat, M.K., Shotan, A., Blondheim, D.S, Kazatsker, M., Dahan, I., Asif, A., Rozenman, Y., Kleiner, Il, Weinstein, J.M., Frimerman, A., Vasilenko, L., Meisel, S.R. (2016). Non-invasive lung impedance-guided preemptive treatment in chronic heart failure patients: A randomized controlled trial (IMPEDANCE-HF Trial). *Journal of Cardiac Failure, 22*(9), 713-722.

Shochat, M.K., Shotan, A., Blondheim, D.S, Kazatsker, M., Dahan, I., Asif, A., Rozenman, Y., Kleiner, Il, Weinstein, J.M., Frimerman, A., Vasilenko, L., & Meisel, S.R. (2016). One year follow up after termination non-invasive lung IMPEDANCE-Guided preemptive treatment in chronic heart failure patients: a randomized controlled trial (IMPEDANCE-HF Trial). *Journal of Cardiac Failure, 22*(8), S14.

Shapiro, M., Bires, A. M., Waterstram-Rich, K., & Cline, T. W. (2017). Improving clinical outcomes for patients with class III heart failure. *Critical Care Nursing Quarterly, 40*(2), 111-123.

Smith, M.J. & Liehr, P.R. (2014). *Middle range theory for nursing* (3rd ed.). New York:

Springer Publishing Company, LLC.

Tsai, T. C., Joynt, K. E., Wild, R. C., Orav, E. J., & Jha, A. K. (2015). Medicare's Bundled Payment initiative: most hospitals are focused on a few high-volume conditions. *Health Affairs (Project Hope), 34*(3), 371-380.

Tung, Y.-C., Chou, S.-H., Liu, K.-L., Hsieh, I.-C., Wu, L.-S., Lin, C.-P., & Chu, P.-H. (2016). Worse prognosis in heart failure patients with 30-day readmission. *Acta Cardiologica Sinica, 32*(6), 698–707.

Volodarskly, A., Nazeer, H., Rosen, L., Patel, A., & Jermyn, R. (2017). Thoracic impedance & pulmonary artery pressure monitoring in prevention of heart failure hospitalization. *Journal of Cardiac Failure, 23*(8), S88.

Whittemore, R. & Knafl, K. (2005). The integrative review: updated methodology. *Journal of Advanced Nursing, 52*(5), 546-553.

Wilkoff, B., Auricchio, A., Brugada, J., Cowie, M., Ellenbogen, K.A., Gillis, A.M. Hayes, D.L., Howlett, J., Kautzner, J., Love, C.J., Morgan, J.M., Priori, S.G., Reynolds, D.W., Schoenfield, M.H., & Vardas, P.E. (2008). HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDS): Description of techniques, indications, personnel, frequency and ethical considerations: Developed in partnership with the Heart Rhythm Society (HRS) and the European Heart Rhythm Association (EHRA); and in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), the Heart Failure Association of ESC (HFA), and the Heart Failure Society of America (HFSA). Endorsed by the Heart Rhythm Society, the European Heart Rhythm Association (a registered branch of the ESC), the American College of Cardiology, the

American Heart Association. *Europace, 10*(6).

Wood, M.A., Ellenbogen K.A. (2002). Cardiac pacemakers from the patient's perspective. *Circulation, 105*(18), 2136-2138.

Yancy, C.W. (2017). 2017 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure. *Circulation, 137*(3).

Yu, C.M., Wang, L., Chau, E., Chan, R.H., Kong, S.L., Tang, M.O., Christensen, J., Stadler, R.W., & Lau, C.P. (2005). Intrathoracic impedance monitoring in patients with heart failure: Correlation with fluid status and feasibility of early warning preceding hospitalization. *Circulation*(112), 841-848.

Zaccagnini, M.E., White, K.W. (2014). *The Doctor of Nursing Practice Essentials* (Second ed.). Burlington, MA: Jones & Bartlett Learning.

Appendices

A. Evidence for Impedance Monitoring

B. IRB Approval Documentation

C. CITI Certificate

Appendix A

Table 2. Evidence for Impedance Monitoring

Name: Evaluating Impedance Monitoring on Readmissions for Patients with Heart Failure with Reduced Ejection Fraction (HFrEF)

Clinical Question: In patients with HFrEF, who have an impedance monitoring device, does impedance monitoring reduce 30 day hospital readmission rates?

Clinical Question: In patients with HFrEF who have an impedance-monitoring device, does impedance monitoring impact quality of life?

Title/ Author/ (year)	**Study Purpose/ Objective (s)**	**Design, Sampling Method, & Subjects**	**LOE**	**Intervention & Outcomes**	**Results**	**Study Strengths & Limitations**
1. 2007 ACC/AHA/HFSA focused update of the 2013 ACCF/AHA guideline for the management of heart failure. **Yancy, 2017**	This document is an updated version of the 2013 HF guidelines	Clinical Practice Guidelines	Level I	This document services as the most updated version of the clinical practice guidelines for HF management.	The guidelines do not discuss impedance monitoring in any form at this time for management of HF	Strength: this is the highest-level document and is considered the standard for clinicians in managing heart failure Limitation: Does not discuss impedance monitoring as an alternative modality to identification of HF
2. Device diagnostics and early identification of acute decompensat	The purpose of this article was to synthesize the	Systematic Review of 24 studies pertaining to device diagnostics	Level I	This article synthesized the randomized controlled trials	Device diagnostics showed a strong correlation with	Strengths: This study supports the importance of device diagnostics

ed heart failure: a systematic review **Blair, T.** (2014)	literature and its principle objective was to determine if device diagnostics can identify HF exacerbations	and impact on patient data. The articles that were reviewed were obtained using Cumulative Index to Nursing and Allied Health Literature, MEDLINE, PubMed and ClinicalTrials.gov		regarding the efficacy of device diagnostics and how they can identify heart failure exacerbations in the clinical setting	established HF biomarkers and hemodynamic measures. This indicates that device diagnostic parameters predict impending HF much earlier than traditional methods of monitoring.	to identify HF exacerbations and prevent hospitalizations. <u>Limitations:</u> More studies are needed to review the device diagnostics. Bias was noted towards Medtronic devices because the literature available on this topic was primarily from studies using Medtronic devices.
3. Early identification of asymptomatic subjects at increased risk of heart failure and cardiovascular events: progress and future directions. **Coller, J.M., Campbell, D.J., Krum, H., Prior,**	The purpose of this article is to review the current tools that are used to identify HF including biomarkers and EKG's and device diagnostics. Its objective was to encourage an agreed	This study was a systematic review of multiple studies.	Level I	This article discussed the need for a screening tool for patients with heart failure and specifically talked about biomarkers and the SCREEN-HF trial taking place in Australia. It also	This article is helpful because it identified the continued need for screening and monitoring of patients with HF. Article conclusions were that early	<u>Strengths:</u> The literature and most up to date studies were reviewed and reported in this systematic review. <u>Limitations:</u> This study was not able to identify a single

D.L. (2013)	policy and screening tool to identify patients with HF.			reviewed the current published evidence for screening and addressed barriers and recommendations for future research	intervention in asymptomatic cardiac pathology can improve clinical outcomes in many situations.	screening tool, but was able to encourage the need for continued research to identify a screening tool.
4. The lung impedance monitoring in treatment of chronic heart failure (the LIMIT-CHF study). **Domenichini, G., Rahneva, T., Diab, I. G., Dhillon, O. S., Campbell, N. G., Finlay, M., & ... Finlay, M. C.** (2016)	The purpose of this trial was to evaluate the impact of alerts on preventing HF hospitalizations. The objective was to reduce readmissions.	Randomized controlled trial. Chronic HF patients with OptiVol or CorVue capable implantable cardioverter-defibrillators were randomized to either the active group (IIM alarm turned on and diuretic dose increased by 50% for 1 week in the event of alarm sounding) or the control group (alarm turned off). Primary endpoint was HF hospitalizations per patient at 1 year.	Level II	This study (LIMIT-CHF) evaluated the use of alerts in guiding HF treatment and to prevent HF hospitalizations. This study did not reduce emergency HF treatment but did have an impact on quality of life.	Results: 80 patients included in the study, 71 reached 1 year follow-up. There was a total of 11 HF hospitalizations in the active group vs. 6 in the control group without a significant difference in the number of episodes per patient. A decreased trend in MLWHF scores was found in the active group compared to an	Strengths: This was a randomized controlled trial that did show an impact on impedance monitoring on quality of life Limitation: The main limitation is related to the relatively high number of IIM alerts not detected and consequently not treated as per protocol. This may have reduced the potential benefit of alert guided treatment.

					increase in the control group.	
5. Correlation between pulmonary artery pressure and thoracic impedance: Insights from daily monitoring through an implanted device in chronic heart failure. **Perego GB, Oldani M, Pellegrini D, Brasca FMA, Malfatto G, Villani A, Brambilla R, Rella V, Parati G** (2017)	The purpose of this study was to observe the impact of cardiomems and measurement of Pulmonary Artery Pressures (PAP) on thoracic impedance.	Prospective Observational Study/Cohort Study of 10 patients with reduced ejection fraction, previously implanted with an ICS capable of measuring thoracic impedance. These patients were implanted with CardioMems and both impedance and Pulmonary artery pressures were remotely monitored daily. Investigators were blind to the pulmonary artery pressures for the first three months, then this level was used to guide therapy.	Level II	Results: Strict correlation between LV filling pressures and lung water content, however there is a limited value in predicting episodes of thoracic impedance decrease.	This article supports the need to perform impedance monitoring in patients with heart failure to prevent exacerbations.	<u>Strengths:</u> Supports the concept that impedance monitoring can predict fluid overload in patients with heart failure. <u>Limitations:</u> The study population of 10 patients may have been why the study was not able to see a significant ability to prevent exacerbations. Also, all of the study participants were males, so gender related differences cannot be excluded. Also, variations of thoracic impedance and pulmonary artery pressures

						were defined if they lasted greater than 7 days, but also may have influenced the study results.
6. An improved algorithm calculated from intrathoracic impedance can precisely diagnose preclinical heart failure events: sub-analysis of a multicenter MOMOTARO (Monitoring and Management of OptiVol Alert to Reduce Heart Failure Hospitalization) trial study **Miyoshi A, Nishii N, Kubo M, Okamoto Y, Fujii S, Watanabe A, Okawa K, Kawamoto K, Morita H, Ito H** (2017)	This study purpose was to review a new algorithm that can be used to calculate impedance and its objective was to reduce HF hospitalization	Randomized Controlled Trial. Study consisted of 195 patients who had been implanted with a high-energy device.	Level II	MOMOTARO trial in Japan assessed the potential that fluid index could predict fluid accumulation /HF and algorithm modification to reduce the number of false positive threshold-crossings for HF and to accurately diagnose fluid accumulation in patients baseline and alert.	Supports the need to assess the fluid index to predict accumulation of fluid. There were 154 primary HF events that were detected with the previous algorithm (Optivol 1.0), and no significant difference of the BNP between the baseline and alert. Using the modified algorithm, only 37 reached the threshold and the log BNP was significantl	<u>Strengths:</u> Large randomized controlled trial in Japan and could represent a new way to detect impending HF with improved reliability compared to the previous Optivol Algorithm. <u>Limitations:</u> Several limitations of the study include that this is a simulation, and a prospective clinical study is required to conclude whether the modified algorithm reduces false-

					y higher in these 37 events compared with the baseline value.	positives. Also, raw data for patients with HF hospitalizations without threshold-crossing events was not retained as a control. Lastly, many factors can impact fluid retention including infection, pneumonia and anemia and this algorithm cannot detect between these other pathological conditions.
7. Non-invasive lung IMPEDANCE-Guided preemptive treatment in chronic heart failure patients: A randomized controlled trial **Michael Kleiner Shochat M, Shotan A, Kazatsker**	This trial's purpose was to measure the degree of pulmonary congestion with non-invasive impedance and its objective was to reduce HF hospitalizations.	Randomized Controlled Trial. 256 patients from 2 medical centers with chronic HF and EF <35% in NYHA class II-IV who were admitted for AHF within 12 months were recruited. Patients were	Level II	IMPEDANCE-HF trial results show that lung impedance guided treatment reduces hospitalizations for heart failure and decreases HF-related mortality. RCT. There were 67 (monitored	This article supports impedance monitoring and determined that it is the key determinant of HF hospitalizations.	<u>Strengths:</u> This study supports the use of impedance monitoring and encourages continued research on non-invasive technologies. <u>Limitations:</u> No limitations

M, Asif A, Kleiner I, Weinstein JM, Dahan I, Blondheim D, Meisel S (2017)		randomized into the control and therapy group. The therapy group had noninvasive lung impedance measures performed and followed for at least 12 months. Patients were blind to their assignment group. Primary endpoint was AHF hospitalizations and secondary endpoint was all-cause hospitalizations and mortality.		group) v. 158 (control group) AHF hospitalizations during the first year, and 211 v. 386 AHF hospitalizations during the entire follow-up among the monitored patients. During the follow-up there were 42 and 59 deaths. 13 and 31 resulting from HF. Results validate the concept that lung impedance preemptive treatment reduces hospitalizations and incidence of HF, as well as CV and all-cause mortality.		were discussed.
8. One year follow up after termination non-invasive lung impedance-guided preemptive	This one-year follow up study was after the conclusion of the trial and demonstrate	Randomized Controlled Trial. This article reviews the same population as the above and is the 1 year	Level II	The IMPEDANCE-HF trial is the first lung-impedance trial demonstrating that this type of	This trial was a follow-up to the monthly impedance monitoring program and	<u>Strengths:</u> This trial is pivotal in management of HF because it supports the need for preventive

treatment in chronic heart failure patients: a randomized controlled trial (impedance-HF trial) **Shochat MK, Shotan A, Kazatsker M, Asif A, Dahan I, Kleiner I, Blondheim D, Weinstein JM, Meisel S** (2017)	d the impact of this monitoring on survival.	follow-up.		guided pre-emptive therapy of worsening pulmonary congestion prevents HF hospitalizations in HF, reduces all-cause, CV, and HF mortality in these patients. Lung impedance was performed with a new noninvasive high-sensitive device.	supports the importance of monthly impedance monitoring.	monitoring. It also encourages continued research in this area of medicine. <u>Limitations:</u> No limitations were discussed.
9. Analysis of different device-based intrathoracic impedance vectors for detection of heart failure events (from the Detect Fluid Early from Intrathoracic Impedance Monitoring Study). **Heist, E. K., Herre, J. M., Binkley, P. F., Van Bakel, A. B., Porterfield,**	The purpose of this article was to evaluate algorithms used to detect pulmonary congestion and to achieve an acceptably low false-positive rate.	Prospective Multi-Center study of multiple intrathoracic impedance vectors to detect pulmonary congestion events	Level III	162 patients were enrolled, 80 with ICDs and 82 with CRT-Ds all with greater than or equal to 1 pulmonary congestion event.	An alternative algorithm was used to detect pulmonary congestion and resulted in a sensitivity of 21.6% and a false-positive rate of 0.9% per patient year. The DEFEAT-PE algorithms	<u>Strengths:</u> compared to other cohort studies this study analyzed multiple intrathoracic impedance vectors from multiple centers <u>Limitations:</u> Relatively small sample size and inability to have a high sensitivity

J. G., Porterfield, L. M., & ... Pavri, B. B. (2014).					resulted in low sensitivity for the prediction of heart failure events and able to achieve an acceptably low false-positive rate. This algorithm was ultimately approved by the USDA.	for the prediction of HF events.
10. Retrospective application of program to access and review trending information and evaluate correlation to symptoms in patients with heart failure criteria for the remote management of patients with cardiac resynchronization therapy. **Brasca, F. A., Franzetti, J., Rella, V., Malfatto, G.,**	The purpose of this article was to review retrospective data and evaluate the correlation between symptoms of HF and the ability to remotely manage HF symptoms.	Retrospective Analysis. The PARTNERS HF trial was evaluated to see if the criteria to detect initial decompensating in moderate HF patients was possible under remote monitoring.	Level III	The PARTNERS HF criteria was retrospectively applied to 1860 transmissions from 104 patients who were enrolled in the telemedicine after cardiac resynchronisation therapy program. The criteria were tested to predict acute decompensation occurring the 15 days following a transmission.	In 441 cases, acute HF was diagnosed after the index transmission. This means that PARTNERS HF criteria could identify HF patients who subsequently developed acute decompensation and these results	<u>Strengths:</u> This study showed how device data can be utilized to provide objective data to patient symptoms. <u>Limitations:</u> More research is needed to correlate device data with symptoms and the ability to treat HF exacerbations through remote managemen

Brambilla, R., Facchini, M., & ... Perego, G. B. (2017)					warrant prospectiv e studies to be done applying these criteria to remote monitoring .	t.
11.Thoracic impedance & pulmonary artery pressure monitoring in prevention of heart failure hospitalizatio n. **Volodarskiy, A., Nazeer, H., Rosen, L., Patel, A., Jermyn, R.** (2017) **remove***	This study's objective was to evaluate whether thoracic impedance and pulmonary artery pressure correlate and predict HF hospitalizati ons.	Cohort Study of 15 patients that were implanted with CardioMems at euvolemic states and a concurrent Medtronic Automatic Implantable Cardioverter-Defibrillator with OptiVol sensore were recruited	Level III	Data was abstracted from the patient's devices and charts were reviewed for hospitalizatio ns for heart failure. An analysis was performed for an overall correlation between the two modalities as well as any changes in modality in the 14 days preceding the hospitalizatio ns.	Results: The 15 patients were average age of 65.7 years and predomina tely male with an average EF of 34%. 7 of the 15 patients had 11 hospitaliza tions for HF. No significant changes in either the PA diastolic pressure or impedance were discovered .	Strengths: These outcomes in the small cohort study supported the use of device monitoring, Limitations: sample size was a limitation and it was not randomized.
12. Device monitoring of heart failure in cardiac resynchroniza tion therapy	The purpose of this single-center cohort study was to evaluate	Prospective Cohort Study. 80 patients were prospectively enrolled during	Level IV	This was a prospective study of 80 HF patients that confirmed the feasibility	Results: during follow-up 56 events of fluid index alerts were	Strengths: include the feasibility to implement a device monitoring

device recipients: a single-center experience with a novel multivector impedance monitoring system. **Forleo, G. B., Panattoni, G., Schirripa, V., Papavasileiou, L. P., Della Rocca, D. G., Politano, A., & ... Romeo, F.** (2013)	device monitoring in CRT HF patients.	implantation of biventricular defibrillators with multivector impedance monitoring capability.		and clinical usefulness of an impedance monitoring system, however, recommended larger studies to be performed. The 80 patients were prospectively enrolled also and clinical heart failure status and impedance data were assessed during follow-up and if patients presented with an alert or heart failure deterioration.	identified in 29 patients. Actual HF events occurred in 23 patients (worsening signs and symptoms). False positives occurred in 23 of the 80 patients. Decompensation resulted in 13 hospitalizations and 7 of the 13 were preceded by an alert.	system but recommended that further studies be done. <u>Limitations:</u> false positives do occur.
13. Determining the effectiveness of impedance monitoring in heart failure patients with implanted cardiac defibrillators. **Franchuk, A.** (2017)	The purpose of this article was to determine the effectiveness of impedance monitoring on heart failure and to assess patient's perceptions of self-care.	Cohort Study of 25 patients	Level IV	A comprehensive literature search was done using CINAHL plus full test, PubMed, and Google Scholar prior to the study. This study was performed at a large private	21 study participants were male and 4 were female with the mean age of 69.5. Study results showed that patient's confidence increased	<u>Strengths:</u> This article evaluated self-care and the impact device monitoring can have on helping patients to improve self-care methods. <u>Limitations:</u> Data

				cardiology practice. Participants were recruited during a device interrogation of their ICD or over the phone if the impedance alert was triggered. After 30 days a chart review was performed to assess if any intervention occurred in direct relation to the patient's heart failure. A pre and post test was also administered to all patients (SCHFI test).	related to management of symptoms due to the surveillance of impedance monitoring.	collection only occurred at one office. Time constraint was also a study limitation because this study was performed during an academic year. Attrition rates were high for the phone recruitment resulting in a smaller sample size.
14. Improving Clinical Outcomes for Patients with Class III Heart Failure. **Shapiro, M., Bires, A. M., Waterstram-Rich, K., & Cline, T. W.** (2017)	Study objective was that patients with Class III chronic HF who received interventions in the form of an implanted CorVue ICD and home health	Retrospective Chart Review	Level IV	A retrospective chart review compared the 30-day readmission rates and mortality rates. An analysis and comparison of 120 patients. The patients were divided into	Results: No patients with CorVue experienced a 30-day readmission. In contrast, 14 of 60 patients in the control group did experience	<u>Strengths:</u> This supports the need to implement a device monitoring program. More studies are needed to determine with interventions have the

	care would have fewer 30-day readmissions than patients who only received home care. Principle outcome of interest was to see if patients with CorVue ICD have lower 30-day readmission rates than patients without the device.			a control group and a study group with 60 patients in each.	a 30-day readmission.	greatest financial impact as well as patient outcomes improvement. Limitations: Additional studies recommended, the study time period was 90 days with a small sample size therefore validity cannot be certain or generalized.

Appendix B

IRB Approval Letter

June 1, 2018

IRB Application 3363: Evaluating Increased Impedance Monitoring to Reduce Readmissions for Patients with Heart Failure with Reduced Ejection Fraction

Dear Abigail Newton,

The Liberty University Institutional Review Board has reviewed your application in accordance with the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) regulations and finds your study does not classify as human subjects research. This means you may begin your research with the data safeguarding methods mentioned in your IRB application.

Your study does not classify as human subjects research because it will not involve the collection of identifiable, private information.

Please note that this decision only applies to your current research application, and any changes to your protocol must be reported to the Liberty IRB for verification of continued non-human subjects research status. You may report these changes by submitting a new application to the IRB and referencing the above IRB Application number.

If you have any questions about this determination or need assistance in identifying whether possible changes to your protocol would change your application's status, please email us at irb@liberty.edu.

Sincerely,

Appendix C

CITI Certificate