Differences in Device Acceptance in Individuals with Pacemakers and ICDs

By

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December 2022

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Abstract

Background: Heart disease is the leading cause of death in the United States (Benjamin et al., 2019) and triggers a host of concerns about virtually all aspects of a patient's life including physical and psychological health. Treatment for heart conditions often utilizes implantable technology, such as ICDs and pacemakers, that reduce mortality (Al-Khatib et al., 2017; Simon & Janz 1982). Research on this technology and its effect on QoL is mixed, with some findings indicting positive effects of ICDs on QoL, while others have shown an increase of psychological disorders and decreased QoL (Magyar-Russell et al., 2011). Device specific QoL-related concerns include acceptance of the technology into the patient's life (Burns, Serber, Keim, & Sears, 2005) and fear, worry, or avoidance related to ICD shocks (Ford et al., 2012). Health care providers typically obtain information from the device during in-clinic visits to better understand the course of the disease and guide treatment decisions. More recently, continued technological advances allow caregivers to monitor a patient's device remotely (Braunschweig, Anker, Proff, & Varma, 2019). This new method of patient care reduces health care costs, reduces the number of required clinic visits and has comparable survival rates as compared to in clinic visits

(Parthiban et al., 2015). Remote monitoring may be particularly valuable in single-payor health systems such as Canada. Remote monitoring has been shown to be comparable to usual care for ICD patients, but patient reported outcomes such as QOL, are understudied (Versteeg at al., 2014). **Purpose:** The current study seeks to examine cardiac patients with an implantable device, ICDs or pacemakers, who have received remote monitoring and compare differences between these groups and change over time on patient reported outcomes such as patient acceptance, health security, and shock anxiety. There were three hypotheses for the study 1) Individuals with ICDs will have lower device acceptance and health security than individuals with pacemakers. 2) Both groups (ICDs and Pacemakers) will have lower levels of device acceptance and health security at baseline as compared to 12-month follow-up. 3) ICD patients will have higher shock anxiety at baseline as compared to 12-month follow-up. **Methods**: Data was collected on 176 participants who were part of the Remote Patient Management for Cardiac Implantable Electronic Devices (RPM-CIED- Pilot). Three analyses were conducted including a principal components analysis on the novel construct of Health security, a 2x2 mixed model ANOVA and a dependent samples t-test. **Results**: Health Security was found to be comprised of 2 factors: Positive and Negative Outlook. Health Security total score significantly decreased over time for both pacemaker and ICD patients. Device acceptance did not differ over time or by device type. There was no change in shock anxiety over time. **Conclusion**: Device specific QoL remained stable during the one-year study period and did not differ significantly based on device type. Patient reported health security declined and may warrant attention in future clinical and research considerations to examine its potential utility and its relationship to QOL.

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A Thesis

Presented to the Faculty of the Department of Psychology

East Carolina University

In Partial Fulfillment of the Requirement for the Degree

Doctor of Philosophy in Health Psychology, Clinical Health

by

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December 2022

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Chapter 1: Introduction

Coronary Artery Disease

Cardiovascular disease (CVD) types can be broadly categorized as electrical, circulatory, and structural problems that can have potentially life-threatening consequences. Arrhythmias are the result of an electrical problem that may cause the heart to beat either more quickly than normal (tachycardia), slower than normal (bradycardia), or erratic (fibrillation). Some forms of these arrhythmias place individuals at risk for sudden cardiac arrest (SCA), which results in asystole and cessation of blood flow to vital organs. SCA is the primary driver of why CVD is the leading cause of death in the United States (Benjamin et al., 2019) and the second leading cause of death in Canada (Robitaille, McRae, & Toews, 2017). SCD was identified on 13.4% of death certificates in 2016 in the United States (Benjamin et al., 2019).

Individuals who survive SCA require continued management of their heart disease as they are still at risk for SCD, or a future SCA, and are more likely to experience and to develop heart failure (HF). With a large portion of the baby boomer generation surpassing the age of 65 and improved survival rate of cardiac patients due to advances in treatment, the number of patients with risk of SCA and heart failure is expected to increase (Mozaffarian et al., 2016). Advances in technology has led the way to implantable devices, which are the modern front-line treatment approach for SCA and HF.

Implantable Device Technology

Both pacemakers and implantable cardioverter defibrillators **(**ICD) are used in the management of cardiac disease in patients with conduction anomalies. These devices have improved over time and are effective at addressing a patient's disease burden and symptoms. The

type of device implanted often differs depending on the type and severity of heart disease. Both devices are proficient at managing specific deficits associated CVD.

Pacemakers were first introduced in the 1950's and are implanted in patients with slower-than-desirable heart rates. The device sends electrical pulses to the heart to restore a normal rate and improve response to physical activity. Pacemakers can differ by pacing site within the heart and type of pacing. There are several types of pacemakers: single chamber, dual chamber and biventricular (cardiac resynchronization therapy). A single chamber pacemaker sends electrical impulses to the right ventricle, whereas a dual chamber sends electrical impulses to the right ventricle and/or right atrium to help regulate the contractions between the two chambers. Biventricular pacemakers use an additional lead that activates the left ventricle to help both ventricles contract more synchronously. Pacemakers are also often implanted in individuals with sinus node dysfunction atrioventricular block and can help prevent ventricular tachyarrhythmias – overall, the device has been effective in addressing patient health concerns (Gregoratos, 1999).

Approximately 70-80% of permanent pacemakers are implanted in individuals 65 years or older (Gregoratos, 1999). Pacemakers reduce overall mortality in elderly patients and even help avert cardiac symptoms with persistent beneficial effects observed up to ten years later (Shen et al., 1994). However, some patient characteristics can influence patient survival, including advanced age and comorbid heart conditions such as congestive heart failure (Simon & Janz 1982). Despite evidence of life extension, these individuals may require additional treatments to manage their disease states.

In contrast, an ICD monitors heart rhythm for potentially life-threatening arrhythmias that are excessive in rate and/or irregular in rhythm. The ICD can provide diagnostic information and treatment responses using low energy pacing or high-energy shock to terminate arrhythmias,

referred to as an appropriate shock. However, in monitoring a patient's heart rhythm, an ICD may falsely detect a life-threatening arrhythmia and deliver a shock to the patient unnecessarily, known as an inappropriate shock. Though modern ICDs are now capable of delivering the same treatment as a pacemaker, reducing the differences between devices, ICDs are distinguished by this ability to deliver shocks to terminate potentially life-threatening arrhythmias. Therefore, ICDs are typically implanted in individuals with more life-threatening arrhythmia potential who are at higher risk for SCA.

ICDs are effective in reducing mortality at multiple stages of treatment and are implanted as primary prevention and secondary prevention. In terms of primary prevention, an ICD would be implanted when the patient has indicators or conditions that put them at risk for arrhythmias and SCA such as significantly diminished ejection fraction. As an example of secondary prevention, patients with a history of documented ventricular arrhythmias may be given an ICD to prevent SCA. Meta-analyses have found a survival benefit from SCA for ICDs for both primary and secondary prevention (Al-Khatib et al., 2017; Qian et al., 2016; Wolff et al., 2017). Further, ICDs have been shown to be effective in reducing all-cause mortality as well (Al-Khatib et al., 2017). Despite the medical success of these devices, some patients have difficulty adjusting to life after ICD implantation.

Pacemakers and Psychological Factors

The introduction of pacemakers and ICDs has increased life expectancy for individuals with heart disease, however, device treatment incurs unique challenges in mental and physical recovery. Behavioral factors, such as engagement in physical activity, have also played a role in successful living with a device. Consequently, this research has shifted attention to quality of life

(QoL) for these individuals, including components such psychological concerns and behavioral patterns.

As previously mentioned, pacemakers have demonstrated a survival benefit, but they have also been shown to improve short term QoL. Specifically, pacemakers consistently have demonstrated an improvement in health-related quality of life (HQoL) and QoL in patients for six months (Mlynarski, Wlodyka, & Kargul, 2009) and even up to a year post implantation (Lamas et al., 1998; van Eck et al., 2008;). There is some debate in the literature as to whether the type of pacing of the device has a relationship HQoL, with some studies finding no relationship (Deharo et al., 1996; Lamas et al., 1998; Newman et al., 2003) and others showing improvements in dual chamber pacemakers (Fleischmann et al., 2006; Lamas et al., 2002).

Next, research has been conducted to ascertain the long-term effect on QoL of pacemaker implantation. In one study, pacemaker patients were assessed over a 7.5-year period and it was found that patients experienced an increase in QoL 1-year after device implantation as compared to pre-implant scores (Udo et al., 2013). However, they found that QoL then gradually declined over the course of the study, with QoL at 3 years post implantation being lower than pre-implant QoL. While some subscales of the Short Form-36 (a measure of QoL) and other HQoL remained high throughout the follow up, patients reported that physical functioning declined after an initial improvement. Similar results were found in the MOST-trial, with all scales being initially higher after implantation and measures assessing physical functioning decreasing over time (Fleischmann et al., 2006; Lamas et al., 2002).

While there is a benefit of pacemakers medically and on QoL, age plays an important factor in this relationship, as older patients do not appear to have as strong of a response to treatment. Patients over the age of 75 report significantly less improvement in physical

functioning and functional status as compared to younger patients (Fleishmann et al., 2006). Older patients with devices used to treat heart disease may continue to present as worse due to disease progression with age that is accompanied by loss of function. One possible explanation is "frailty syndrome", which denotes that older patients are more likely to experience other health events that can reduce their QoL and longevity, including an increased risk of falls, disability, reduced mobility, and an increase in hospital utilization (Chen, Mao, & Leng, 2014). Frailty has also been correlated with worse QoL prior to device implantation; this could account for differences between older and younger patients that already exist prior to treatment, especially as QoL is also affected by other non-cardiac health complications (Mlynarska, Mlynarski, & Golba, 2018).

Implantable Cardioverter Defibrillators and Psychological Factors

Similar to pacemakers, ICDs have been researched in terms of psychological outcomes as well. ICDs are unique in that they deliver lifesaving shocks as treatment, but many patients develop negative associations with the device due to the shocks. In response, some patients modify their lifestyle to accommodate their device (Ferrick, & Ferrick, 2017). This scenario may cause individuals to become overly sedentary or restrictive as a way to avoid shocks from their ICD; for instance, they may restrict their participation in activities such as driving, rigorous physical activity and sexual relationships (Chandra et al., 2018). Patients often report hesitation with engaging in rigorous physical activity for fear that it will trigger a shock from their device. Nonetheless, observational research has shown that ICD patients between 10 and 60 years old can participate in sports without a sizable risk of experiencing resuscitated arrest or arrhythmia or shock related injury (Lampert et al., 2017). Recent research has begun to utilize ICDs as an activity monitor which has been able to provide information on activity levels and have

determined that the average ICD patient engages in detected movement between 1.5 to 3 hours a day (Sears, Whited, Koehler, & Gunderson, 2015). This is especially concerning as lower levels of physical activity have been linked to an increased mortality risk after two years (Kramer et al., 2015).

The relation between QoL and ICDs appears to be complex, as some evidence has suggested that ICDs have a positive effect on QoL, while other studies indicate no effect. For example, in one study with 80 participants, one-third (34%) of individuals who received an ICD reported an improvement in their QoL, as compared to 44% that reported no change and 20% that reported worse QoL (Dickerson, Kennedy, Wu, Underhill, & Othman, 2010). Differences among groups did not vary by age at implantation, sex, number of shocks or comorbidities. Moreover, more recent research has found that ICD implantation does not have any impact on QoL (Manzoni et al., 2015) for up to one year after device implantation (Dougherty et al., 2016). While the literature has findings to support the neutral and negative effects of an ICD on QoL, there is strong support that QoL is significantly impacted if the individual experiences more than five shocks (Passman et al., 2007). Regardless, QoL in ICD patients have been shown to be comparable to patients prescribed antiarrhythmic medications (Sears, Matchett, & Conti, 2009). Despite QoL being comparable across treatment groups of heart disease patients, ICD patients are still susceptible to psychological disorders.

Psychological disorders are prevalent in individuals with ICDs and can be influenced by the potential of shocks. Estimates of psychopathology based on clinical interview of ICD patients estimate that 11% to 28% of individuals meet criteria for a depressive disorder and 11% to 26% for anxiety disorders (Magyar-Russell et al., 2011). This review also found that estimates increased when only self-report measures are used to assess the presence of a psychological

disorder. The frequency of shocks has been shown to be related to psychological outcomes. Individuals who received two or more appropriate shocks experienced higher levels of shock anxiety and more anxiety than patients who received one or fewer inappropriate shocks (Perini et al., 2017). Patients who received multiple shocks (e.g., 3 in 24 hours or 5 in a year) experienced more psychological distress (Jordan, Titscher, Peregrinova, & Kirsch, 2013). This experience of frequent shocks can also be a traumatic experience and some estimates indicate that 20% of patients endorse some symptoms of post-traumatic stress disorder (Kapa et al., 2010).

In summary, technology continues to reduce mortality and lessen disease burden; however, psychological aspects of cardiac disease significantly impair patient functioning and can lead to a worse prognosis (Sears, et al., 2015). As noted, psychological concerns in ICD patients are common (Magyar-Russell et al., 2011), but improvements in measuring ICD specific concerns have improved the understanding of ICD patient concerns, including shock anxiety and device acceptance.

Shock Anxiety

Shocks delivered via an ICD are necessary for the life-saving properties of defibrillation. Each year, between 4% to 6 % of ICD patients will receive a shock (Sears, Whited, & Volosin, 2015). Individuals who have experienced ICD shocks describe them as a "spasm that caused their entire body to jump" or as being "kicked in the chest by a horse." Patients, on average, have rated shocks as a 6 out of 10 on a pain scale, but are tolerated due to their life saving nature (Ahmad, Bloomstein, Roelke, Bernstein, & Parsonnet, 2000). Despite their utility, 23% of patients reported that they dread the shocks, and 5% reported that the intensity of the shocks were not worth their life-saving qualities and would rather take their chances without them (Dunbar et al., 2012). Advances in device technology reduced psychological impact of ICDs and

have been able to improve the specificity of ICD shocks, resulting in a reduction in the total number of shocks received (Sears, Whited, & Volosin, 2015). Despite these advances, ICD shocks still affect patient behavior and psychological distress (Sears et al., 2018).

The term "shock anxiety" has been developed to describe this commonly reported distress surrounding shocks and associated worry. The term can refer to either the fear or worry about receiving a shock and the avoidance of activities that may trigger the occurrence of a shock. These sentiments have been found in approximately 44% of ICD patients, regardless of their shock history, and 15% say that shocks are highly problematic (Morken et al., 2012). Further, shock anxiety can also be experienced by spouses of ICD patients, sometimes at higher rates than ICD patients themselves (Sowell et al., 2007). Interestingly, interventions that include both the patient and their spouse are more effective at improving depressive symptoms, self-efficacy, outcome expectations and knowledge (Dougherty, Thompson, & Kudenchuk, 2019). This intervention also improved outcomes for partners including a reduction in caregiver burden and an increase in self-efficacy and ICD knowledge. Interventions such as tailored cognitive behavioral therapy are also effective in reducing shock anxiety (Ford et al., 2019; Qintar et al., 2015).

Shock anxiety is influenced by several factors, such as device knowledge, patient attitude, and perceived support. Knowledge about one's own device has a negative relation with shock anxiety and patients who endorsed higher levels of shock anxiety also had lower levels of device knowledge (Wilson et al., 2013). Improved device knowledge is associated with lower levels of shock anxiety and can be derived from a variety of sources, including other patients and physicians, as well as social media outlets and websites (Richards et al., 2016). Patient attitude towards their device and their dependency on their ICD has also been correlated with shock

anxiety and mental QoL (Udlis, 2013). Additionally, patients with higher levels of perceived support from health professionals report lower levels of shock anxiety and lower levels of posttraumatic stress disorder symptoms (Morken et al., 2014).

Characteristics of shocks have also been linked to shock anxiety, including frequency of shocks and time since the last shock. The number of shocks received by the patient, regardless if they were appropriate shocks or not, is associated with higher levels of shock anxiety (Perini et al., 2017). This finding has persisted even with the improvement of ICD programming to reduce the number of inappropriate shocks. In addition, the time elapsed since a patient's last shock has been linked to shock anxiety, indicating that the longer an individual goes without receiving a shock, the lower level of shock anxiety they experience (Sears et al., 2018). However, while there is a reduction in shock anxiety over time, elevated levels of shock anxiety can persist for as much as 24 months after a received shock (Sears et al., 2018).

Patient demographic variables and disease history have been found to influence the level of shock anxiety. African American patients are more likely to report higher levels of shock anxiety than Caucasian patients (Wilson et al., 2013). Additionally, female patients also endorse higher levels of shock anxiety as compared to males (Perini et al., 2017). Younger age is another predictor of shock anxiety, with individuals younger than 50 being more likely to report higher shock anxiety (Perini et al., 2017). Further, patients who received an ICD for secondary prevention have higher levels of shock anxiety as compared to primary prevention (Qintar et al., 2015).

Some studies indicate contrasting results on the relation between shocks and QoL, finding that ICDs improved QoL (Pedersen, et al., 2010). However, Sears and Kirian (2010) posited that the contradicting results of shock on QoL is contingent upon the frequency of shocks

and assessment tools used to measure QoL. General assessments for QoL may not be sensitive enough to detect differences in device disease specific outcomes. These authors suggest that the careful consideration of disease and device-specific metrics will allow for more precise interpretation about the impacts of device technology vs. measures of general psychopathology or global QOL.

ICDs Versus Pacemakers on QoL

Research has investigated whether modern ICDs and pacemakers differed in terms of patient QoL, especially due to ICD shocks. Researchers compared 81 pacemaker patients and 44 ICD patients on QoL (Icelandic Quality of Life Questionnaire), general health QoL (General Health Questionnaire), anxiety (Beck Anxiety Inventory) and depression (Beck Depression Inventory) of patients, and no significant differences were found on measures of these variables (Leosdottir, et al., 2006). Leosdottir and colleagues demonstrated that QoL was comparable across groups, as well as the prevalence of psychological disorders including anxiety or depression. However, QoL was broadly defined and may not have been sensitive to detecting more concerns unique to disease groups.

German researchers have also compared pacemaker and ICD patients, and further split ICD patients into two groups based on shock history (Duru et al., 2001). The three groups: pacemaker (n = 76), ICD no shock (n = 31), and ICD shock (n = 45) were compared using the Hospital Anxiety and Depression Scale (HADS) and the Short Form general health survey (SF-36). No significant differences were detected, however, ICD patients who had received shocks reported more limitations in their leisure activities and higher levels of anxiety about their device not functioning properly or running low on battery power. Shocked ICD participants were more likely to view their device as extending their life and were more interested in attending a support

group. Therefore, shocked ICD patients reported the benefit of protection, but the need for more emotional assistance. This study had several limitations; the groups differed significantly on the time since implantation and response rates of individuals who completed the survey. The measures used, such as the SF-36 or HADS, may not be sensitive enough to detect differences within patients who have cardiac devices, as compared to a QoL survey designed to be used with this population such as measures of device acceptance.

Device Acceptance

Patient acceptance of device technology is described as accommodating and understanding the benefits and detriments of their device, including the improvement of multiple areas of functioning (Burns, et al., 2005). Device acceptance, as measured by the Florida Patient Acceptance Survey (FPAS), consists of four factors: return to functioning, device related distress, positive appraisal, and body image concerns, and is moderately correlated with general QoL measures (Burns, et al., 2005). The FPAS has been translated and culturally adapted for other patient groups (Castillo-Sierra & González-Consuegra, 2018) including those in other countries (Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008; Tripp, Huber, Kuhl, & Sears, 2019). Most individuals are accepting of their device, with 85% of patients experiencing high levels of device acceptance (Morken, Norekvål, Bru, Larsen, & Karlsen, 2014), but device specific measures, such as the FPAS, allow for increased sensitivity in detecting differences in changes in QoL, as well as the potential differences between patients with different device types.

The added specificity of the FPAS has allowed for more precise insight into the influence device acceptance has on other patient variables. For example, patients who endorse low levels of device acceptance also endorse more psychological distress and lower QoL (Versteeg et al., 2010; Versteeg et al., 2012). Similarly, expectations about device and acceptance of their device

has been associated with symptoms of psychological disorders, such as depression and anxiety (Ford et al., 2011; Habibovi´, Pedersen, van den Broek, & Denollet, 2014; James et al., 2012). For instance, patients with anxiety are more likely to have a negative view of their device, focusing more on the constraints of the device and feeling less safe (Lang et al., 2014). If left untreated, anxiety symptoms may persist up to 12 months after ICD patients in half of patients who were anxious at device implantation (Pedersen et al., 2011). Thus, low device acceptance is correlated with poor physical and QoL outcomes, as well as elevated rates of psychological disorders. Consequently, psychological distress and symptoms of psychological disorders can undermine health outcomes (Rozanski, Blumenthal & Kaplan, 1999) and influence patient device acceptance, which has created a cyclical pattern (Pedersen, Spindler, Johansen, & Mortensen, 2009; Pedersen, Spindler, Johansen, Mortensen, & Sears, 2008; Wilson et al., 2013).

Non-psychological factors have also been associated with device acceptance. Identifying as African American (Wilson et al., 2013), older age, not having a partner, symptomatic heart failure, and having ICD concerns have been correlated with poorer device acceptance (Pedersen et al., 2008). Similarly, longer duration since device implant and increased functional capacity are associated with higher device acceptance (James et al., 2012). For instance, patients who experience symptomatic heart failure may have an increased disease burden, which in turn affects their ability to adapt to their device (Burns, et al., 2004). This can create a cyclical pattern as poor device acceptance was associated with more symptomatic heart failure (Ford et al., 2011).

Shock anxiety and device acceptance may have a combined impact on the patient experience. Overall, shock anxiety has a negative relationship with device acceptance (Gallagher et al., 2016; Morken et al., 2014; Wilson et al., 2013). Negative patient attitudes about device

dependency is associated with lower levels of device acceptance, higher shock anxiety and lower QoL (Udlis, 2013). Additionally, younger patients with a high shock history were more likely to have lower levels of device acceptance (Birnie et al., 2009). Fortunately, predictors of positive device acceptance and QoL have also been identified. Social support has shown positive benefits on QoL and device acceptance. Social support is correlated with device acceptance in elderly individuals with pacemakers (De Bardi, Lorenzoni, & Gregori, 2016). Further, constructive support from healthcare professionals had a positive correlation with device acceptance and moderated the relationship between shock anxiety and device acceptance (Morken et al., 2014).

ICD Versus Pacemakers on Device Acceptance

Previous research has demonstrated that device acceptance differs significantly based on the type of cardiac device that is implanted (Burns et al., 2005). These investigators found that ICD patients had the lowest levels of device acceptance compared to ICD Atrioverter (AT) defibrillator and pacemaker patients, with pacemaker patients having the highest levels of device acceptance. Specifically, ICD patients endorsed lower scores on the return to functioning subscale than pacemaker patients. Further, pacemaker patients reported lower device related distress as compared to ICD patients (Burns et al., 2005).

Research with individuals with congenital heart disease also found differences between adults with ICD and pacemakers. Individuals (n = 59) with congenital heart disease who had an ICD reported lower device acceptance, compared to individuals (n = 41) with congenital heart disease who had a pacemaker (Bedair et al., 2015). Further, these individuals endorsed lower levels of quality of life and higher prevalence of depression when compared to individuals who did not have any device. Individuals with low levels of device acceptance had lower mental health scores, higher levels of anxiety, depression than individuals who had high levels of device

acceptance. Lower device acceptance was associated with younger age at the time of the survey, younger age at ICD implantation, and less likelihood to receive appropriate shocks (Bedair et al., 2015).

Existing research suggests that the FPAS has utility as a device specific measure of QoL and allows for increased sensitivity to detect differences within the disease group, between device type, and distinguish changes in health status during treatment. Previously discussed research that did not find differences in QoL (Leosdottir, et al., 2006) may have detected an effect if device specific measures were utilized. While the gap between pacemakers and ICDs is shrinking, these groups may have differed on device specific constructs like device acceptance. Patients are asked to continually integrate more technology into their treatment to increase efficacy and to ease patient burden including the latest technology, remote monitoring.

Remote Monitoring

Remote monitoring was first approved by the Food and Drug Administration (FDA) in 2001 and has been recommended by the Heart Rhythm Society since 2015 (Slotwiner et al., 2015). Remote patient monitoring (RPM) communicates with patient devices to assess a variety of parameters including arrhythmias, heart rate and rhythm, battery life, intracardiac electrograms, patient activity levels, blood pressure, heart failure symptoms (Braunschweig, Anker, Proff, & Varma, 2019). The manufacturers store information received from the device and transmit information to healthcare providers if predetermined criteria are met. Data will also be transmitted in routine intervals, depending on the manufacturers specifications and allow for patients to send data transmission if they would like a professional opinion on their heart's activity (Braunschweig et al., 2019). Scheduled transmission of data has been shown to be more beneficial to treatment, as it aids in early detection of adverse cardiac events (de Ruvo, et al.,

2016; and Varma et al., 2015). Further, a meta-analysis examining seven random controlled trials revealed that RPM and inpatient clinic visits did not differ in terms of mortality, except for one study that showed a survival benefit of RPM (Parthiban et al., 2015). However, there is limited research examining patient reported outcomes (PRO) as a primary measure for ICD patients involved in RPM (Versteeg at al., 2014).

Studies on remote monitoring had concluded positive benefits with more studies examining the effect of RPM on patient reported outcomes. Versteeg and colleagues (2019) examined 595 European heart failure patients from the REMOTE-CIED trial and assessed PROs including heart failure specific health status and device acceptance. Patients were randomized into two groups: 1) in clinic follow-up and 2) RPM follow up over time. The RPM group was assessed at 5 time points over a 2-year period including 2 remote check-ups at 3 months and 6 months, and 3 in-clinic visits at baseline, 12 month and 24 months (Versteeg et al., 2019). The study found no differences in device acceptance or any other PROs between groups at any of the time points (Versteeg et al., 2019). A temporary benefit of device acceptance was found at 6 months for secondary prophylactic, in-clinic only group, but this difference was not present at any other time point (Versteeg et al., 2019). Given the number of comparisons and the lack of a priori hypotheses related to this finding, this finding should be interpreted with caution.

RPM in pacemaker patients has also be examined and found no significant differences between in clinic and telemonitoring groups, with both having an improvement in their QoL (Lopez-Villegas et al., 2018). HQoL was found to be higher in RM patients on the chest discomfort and arrhythmia subscales of the Aquarrel, a pacemaker specific measure over the 6-month study (Comoretto, Facchin, Ghidina, Proclemer & Gregori, 2017). Further, remote monitoring affected the rate of improvement in HQoL in the first 3 months after implantation.

Additional research indicated that patients enrolled in RPM report being highly satisfied with their treatment experience (Timmermans et al., 2018). The median score for satisfaction with remote monitoring technology was 9 out of 10, even with 53% of individuals encountering some issues with their technology. Of this group, 43% of individuals still preferred remote monitoring to in clinic follow up. However, these individuals were more likely to be higher educated, employed, and were less likely to have chronic obstructive pulmonary disease. The majority of patients reported that RPM did not influence their functioning and 30% reported that RPM was a positive influence on their health. However, 20% of individuals did not want to receive RPM which may be filtering patients out on key variables.

Despite these benefits, patient adherence remains a challenge; 47 percent of eligible patients (Akar et al., 2013) and less than half of individuals are adherent to treatment (Varma et al., 2015). Patients when matched for demographic variables were 3.5 times more likely to be enrolled in RPM due to their hospital location, suggesting that they differ in the extent that both clinicians and institutions have adopted this technology. Additionally, patients who lived farther away from their implanting center were more likely to be enrolled in RPM (Akar et al., 2013). As such, RPM may not be an ideal treatment for all patients depending on their attitudes towards treatment. Patient buy-in remains an important factor when assessing the utility of remote monitoring as a viable a treatment and RPM should not be used as a one size fits all solution (Rosman et al., 2018).

Construct Development: Health Security

The experience of living with an ICD or pacemaker has been assessed using both generic and disease specific instruments. The current study attempted to examine the principals of positive psychological benefits from a technological advance with a novel construct: health

security. We defined health security as the perception of reliable and desirable health in the near future. Individuals high on this construct would likely report a positive appraisal about their health prospects and have inherent optimism about their health in general. The concept of health security reflects the broad-based view, consistent with Maslow's hierarchy of needs, and posits once an individual's safety is attained, then there will be increased benefit on psychological outcomes.

Health security theory also draws on the previous literature related to illness perceptions as part of the Common-Sense Model of Health (CSM; Leventhal, Nerenz, & Steele 1984). Illness perceptions are cognitive frameworks that patients use to understand the causes and consequences of illness. Leventhal indicated that patient conceptualization of illness includes aspects spanning identity, consequence, cause, duration and control and covers signs and symptoms of their disease, its perceived impact, cause, time frame of the disease and the extent of control over the disease and its symptoms.

Research on chronic diseases has suggested that illness impact, duration, and control are the key dimensions, and are therefore key components in many psychometric tools, such as the Brief Illness Perception Question (BPIQ; Broadbent, 2015). A recent meta-analysis indicated that beliefs in serious consequences, strong illness identity, and strong emotional representation were strongly associated with depression, anxiety, low QOL, and worse blood glucose levels in previous research across disease states (Hagger, Koch, Chatzisarantis & Orbell, 2017).

The CSM, as measured by the BIPQ, has been utilized in a sample of 585 European ICD patients in the REMOTE-CIED study and has been paired down to two main factors, Control and Consequences (Timmermans, Versteeg, Meine, Pedersen & Denollet, 2017). Further analysis revealed that Consequences is a driving factor of the model and can stand alone as a subscale,

whereas control had only limited support to stand alone. Isolating the consequences factor resulted in a higher internal consistency (α =0.80) as compared the BIPQ as a whole (α =0.69). As a result, the current study will examine illness perceptions from a consequence perspective and consider the novel concept of health security to represent this construct. The unique contribution of health security can be examined as an opportunity to advance our understanding of this potentially useful construct. Patients may also experience a sense of control and consequences via remote monitoring.

The Current Study

The current study evaluated the effects of RPM on patient reported outcomes with patients with pacemakers and ICDs. RPM has gained acceptance as a viable alternative to in-clinic visits; however, more data needs to be collected on how patients are accepting this technology into the management of their disease. The Nova Scotia Health Authority implemented universal use of RPM prior to the study. The ECU Cardiac Psychology Lab was approached to provide an analysis of patient reported outcomes. The constructs of shock anxiety, device acceptance and health security were assessed at baseline and 12-month follow up. A between group (ICD vs. pacemaker), repeated measures (baseline and 12-month) design was analyzed for two of the dependent measures (device acceptance and health security). A repeated measures (Baseline and 12-month) design will be analyzed for shock anxiety in the ICD patient sample.

Aim 1 of this project was to examine differences between groups (ICD and pacemaker) and within group (baseline to 12-month) scores on device acceptance and health security.

Aim 2 of this project was to compare baseline to 12-month scores on shock anxiety.

Chapter II: Methods

Procedure

Data were collected on 176 patients from Nova Scotia Health clinics who received an implantable device. The final sample included 100 with ICDs and 76 patients with pacemakers. All participants were asked to complete the Florida Patient Acceptance Survey (FPAS) and Cardiac Health Security (CHS) measures. Only individuals who received an ICD completed the Florida Shock Anxiety Scale (FSAS) as it deals with device specific shocks that are not present in pacemakers.

After implantation of a pacemaker, patients were seen by providers at three time points: 48 hours after, 10-14 days after and 3 months after. This was comparable to those who received an ICD who were seen within 48 hours of the initial implantation, as well as 6-8 weeks after the device was implanted. Furthermore, shock history for the ICD patients was coded and was examined.

Measures

Demographics. Demographic information was collected on age, sex, device type, time since implantation, and shock history.

Florida Patient Acceptance Survey (FPAS). The Florida Patient Acceptance Survey measures patient acceptance of implantable device treatment including ICD and pacemakers. The scale consists of 15 items measured on a 5-point Likert scale ranging from 1 to 5 from strongly disagree to strongly agree. The scale as a whole demonstrated good internal consistency (α= 0.83; Versteeg et al., 2012). The scale is divided into four subscales all of which also have high internal consistency including Return to Function ($\alpha = 0.89$), Device-Related Distress ($\alpha = 0.79$), Positive Appraisal ($\alpha = 0.82$), and Body Image Concerns ($\alpha = 0.74$).

Florida Shock Anxiety Scale (FSAS). The Florida Shock Anxiety Scale was developed to measure shock related anxiety in individuals who have ICD. The scale consists of 10 questions on a 5-point Likert scale ranging from 1 (not at all) to 5 (all the time). The 10 items load on a single factor, making the scale easy to use and understand by both consumer and assessor. Analysis on the items revealed good internal consistency ($\alpha = 0.89$; Ford et al., 2012). Discriminant and convergent validity data have indicated that the FSAS is negatively correlated with emotional well-being, quality of life, perceived general health, and sense of security while being positively correlated with number of shocks received and perceived disruption of shocks. All these correlations were significant at $p < 0.01$ (Ford et al., 2012).

Cardiac Health Security (CHS). Cardiac health security was a new measure that was piloted during this study. This survey consisted of 24 questions on a 5-point Likert scale ranging from 1 (Strongly Disagree) to 5 (Strongly Agree). This was an exploratory survey that examined the construct of health security. The rationally proposed factor structure is comprised of four variables including Availability, Action, Outcome, and Future Orientation.

Psychometric analysis was performed to determine its factor structure, but this work was not proposed as part of the work of this thesis document. The results of the psychometric testing formed the variable that we have proposed called, “health security”.

Analysis

The study utilized Statistical Package for Social Sciences (SPSS) 26 for all statistical analyses. Data were screened for missing data and univariate outliers. Descriptive statistics were employed to examine scores on the FPAS, FSAS, and CHS and check assumptions of normality, homogeneity of variance and random independent samples. Further, data transformations were

made in the case of a skewed sample. Cronbach alphas were collected to assess internal consistency.

For aim 1, we computed frequencies and descriptive statistics for age, sex, time since implantation and shock history. Any between group differences by device type (ICD vs. Pacemaker) were used as a covariate in subsequent analyses. If analysis did not reveal any covariates, a 2 X 2 Mixed Model Analysis of Variance (ANOVA) was conducted to examine differences between (ICD and pacemaker) and within group (baseline to 12-month) scores on device acceptance and health security. Independent variables included group (ICD and pacemaker) and time (baseline and 12-month follow-up).

It was hypothesized that individuals with ICDs would have lower device acceptance and health security than individuals with pacemakers. Additionally, both groups (ICDs and Pacemakers) would have lower levels of device acceptance and health security at baseline as compared to 12-month follow-up.

For Aim 2, a Dependent t-test was conducted to examine baseline to 12-month follow-up scores on shock anxiety. The independent variable is time and the dependent variable is shock anxiety. It was hypothesized ICD patients would have lower shock anxiety at baseline as compared to 12-month follow-up.

Sample size calculation was completed to determine targeted recruitment goals. To determine these relationships, it was found that 54 participants were needed to achieve 0.95 power to detect a difference using a two-sided hypothesis test with a significant criterion of 0.05 (Faul, Erdfelder, Lang, & Buchner, 2007).

Chapter III: Results

Descriptive statistics. A total of 176 patients, 100 ICD patients and 76 pacemaker patients were included in the study (see Table 1). The majority of the ICD sample were men (71%), middle aged (62.5±11.8 years), and had been living with their device for 2.0±2.3 years. There were 6 device visits due to shock. For pacemaker patients, the majority of the sample were men (63.2%), middle aged (63.4±16.5 years), and had been living with their device for 2.7±3.2 years).

Table 1

Descriptive Statistics

	Age	Women	Time Since Implantation	Shock History
ICD	62.5±11.8	29 (29.0%)	2.0±2.3	6
Pacemaker	63.4±16.5	28 (36.8%)	2.7±3.2	NA

Aim 1a. To assess aim 1, a principal component analysis (PCA) was conducted to identify the underlying factor structure of the novel construct health security. The factor analysis revealed two factors with eigenvalues greater than 2, and two factors were rotated according to a scree-test using an Oblique rotation (see Figure 1). The loadings on these factors accounted for 36.18% of the variance. Only loadings equal or above 0.40 were used to compose the factor scores (Mulaik, 2009). In cases when an item loaded on more than one factor, the item was removed. Question 7, ”I know what action to take if my health condition worsens” failed to load on either factor. Question 15 “I can deal with my condition” and question 20 “I believe I will die of old age” were removed due to complex loading. The PCA was run again, time after the removal of items and resulting in the removal of question 16 “My health condition is stable and will not change much” because of cross loading. Remaining items were examined, and the two

factors assigned a label which were Negative and Positive Outlook (see Table 2). Negative Outlook factor was comprised of 10 items and Positive Outlook consisted of 9 items. Items within Negative Outlook (α = .75) were reverse coded and summed with Positive Outlook (α = .81) to create the total health security variable (α = .78). The final items and factor loadings are provided below.

Figure 1

Scree Plot for Health Security

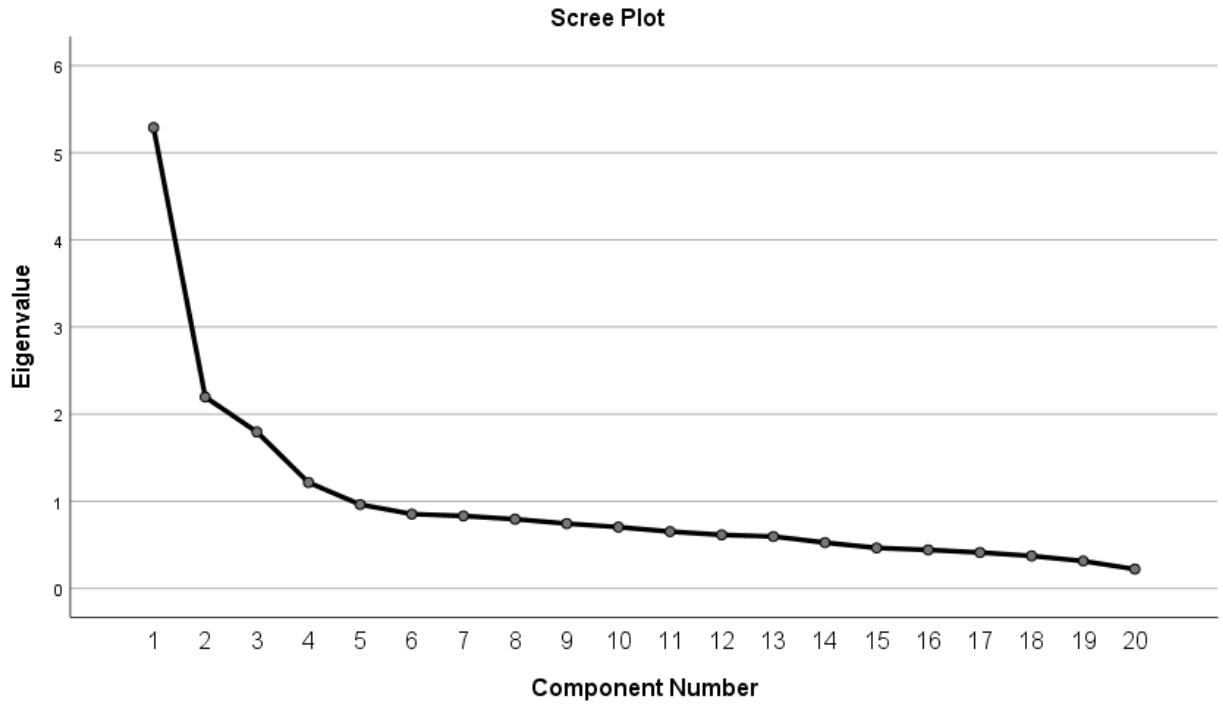

Table 2

Principal Component Analysis Factor Loadings

Number	*Questions*	*Factor 1*	*Factor 2*
1	It's hard to know when I will have "good days" or "bad days" as far as my health problems go.	**.734**	.215
2	I am not sure what to do to be healthy in the future.	**.635**	-.052
3	No one knows how hard it is to live with my condition.	**.593**	-.073
4	My health problems are not predictable.	**.591**	.048

5	I don't know what to do if my condition worsens.	**.562**	-.044
6	I cannot pay for my health care as needed.	**.561**	-.028
7	I do not believe that I will return to full physical functioning.	**.538**	-.057
8	I get mixed messages from different providers about what I need to do to take care of my health	**.537**	-.070
9	I don't know what symptoms of my condition that I should watch for.	**.504**	.030
10	My condition is dangerous to me in the long run	**.497**	-.133
11	If my health condition changes, my health care providers can help me get it back on track.	.079	**-.723**
12	I have the support that I need to be as healthy as possible.	.066	**-.701**
13	What I do now to take care of my health will help my health condition in the future.	-.101	**-.682**
14	If my health condition changes, my family can help me get it back on track.	.141	**-.614**
15	I have access to the right health care providers to take care of my health.	.144	**-.583**
16	If my health condition changes, my faith can help me get it back on track.	-.154	**-.570**
17	If my health condition changes, I can get it back on track.	.196	**-.569**
18	I have the information that I need to be as healthy as possible.	.166	**-.559**
19	I look forward to better health in the future.	-.086	**-.550**

Extraction Method: Principal Component Analysis. Rotation Method: Oblimin with Kaiser Normalization. Loadings; >0.40 bold. Factor 1 Negative; Factor 2 Positive.

Aim 1. Demographic variables including age, sex and time since implantation were assessed prior to analysis and no significant differences between the pacemaker and ICD patients were noted. Prior to analysis, data screening and cleaning were conducted. Missing data was excluded from the analysis. Next, no univariate outliers were detected using a cut off of ±3.29 (Tabachnick & Fidell, 2007, p. 73). Lastly, skew and kurtosis were assessed and found to be within normal limits.

A 2 X 2 Mixed Model Analysis of Variance (ANOVA) was run to determine the effect of device type, time, and interaction effects on health security. There was no significant main effect between device type on health security scores overall ($F(1, 73) = 3.73$, $p = .06$, $\eta^2 = .05$) with ICD ($M = 72.43$) being similar to pacemaker patients ($M = 77.15$; see Table 3). There was a

significant main effect of time on health security ($F(1, 73) = 5.6$, $p = .02$, $\eta^2 = .07$, $d = 0.22$) with baseline scores ($M = 75.85$) higher than follow-up scores ($M = 73.28$) with a medium effect size. Also, there was not a significant interaction between device type X Time on health security scores ($F(1, 73) = .09$, $p = .76$, $\eta^2 = .001$). The assumption for homogeneity of variance was met. Descriptive statistics showed that ICD patients had higher levels of health security at baseline (M =73.56) than follow-up ($M = 71.29$); pacemakers patients showed a similar pattern with health security at baseline ($M = 78.62$) as compared to follow-up ($M = 75.68$). This finding indicates that health security for both groups decreased over time. These results indicate that health security decreased overtime for both pacemaker and ICD patients indicating that they were less secure in their health (see Figure 2).

Figure 2

Cell Means of Health Security by Time and Device Type

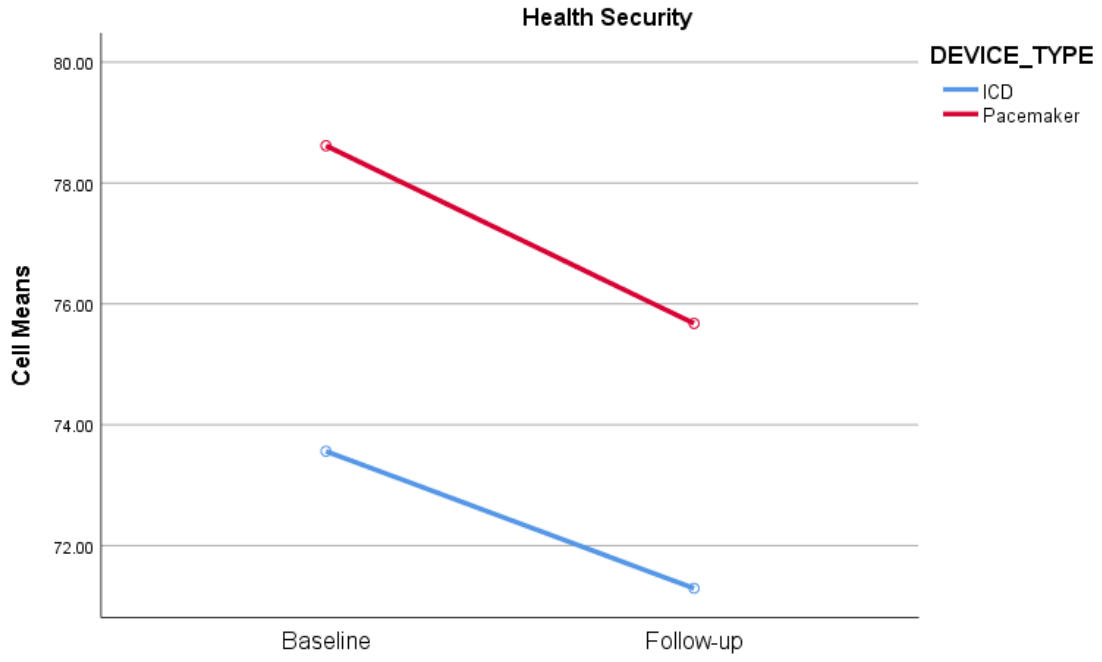

Table 3

Health Security Multiple Table for ANOVA

Source	*df*	*F*	*p*	η^2	*d*
Between Subjects					
Device type	1.00	3.73	.06	.05	
Error (Device type)	1				
Within Subjects					
Time	1.00	5.6	.02***	.07	.22
Time x Device type	1.00	.09	.76	.001	
Error	73				

*** p < .05

A second 2 X 2 Mixed Model (ANOVA) was run to determine the effect of device type, time, and interaction effects on device acceptance. There was not a significant main effect between device type on device acceptance scores overall ($F(1, 73) = 2.02$, $p = .16$, $\eta^2 = .03$) with ICD ($M = 77.32$) being similar to pacemaker patients ($M = 81.81$; see Table 4). There was also not a significant main effect of time on device acceptance ($F(1, 73) = 1.89$, $p = .17$, $\eta^2 = .01$, $d = -0.14$) with baseline ($M = 78.29$) being similar to follow-up ($M = 80.42$). Additionally, there was not a significant interaction between of device type and time on device acceptance scores ($F(1, 73) = .34$, $p = .56$, $\eta^2 = .004$), suggesting there were scores were similar between pacemakers and ICD patients for device acceptance. The assumption for homogeneity of variance was met.

Descriptive statistics showed that ICD patients had similar levels of device acceptance at baseline (mean =75.85) than follow-up (mean = 78.78); pacemakers patients showed a similar pattern with device acceptance at baseline (mean = 81.23) as compared to follow-up (mean = 82.4). Device acceptance remained stable overtime and did not differ between pacemaker and ICD patients (see Figure 3).

Figure 3

Cell Means of Device Acceptance by Time and Device Type

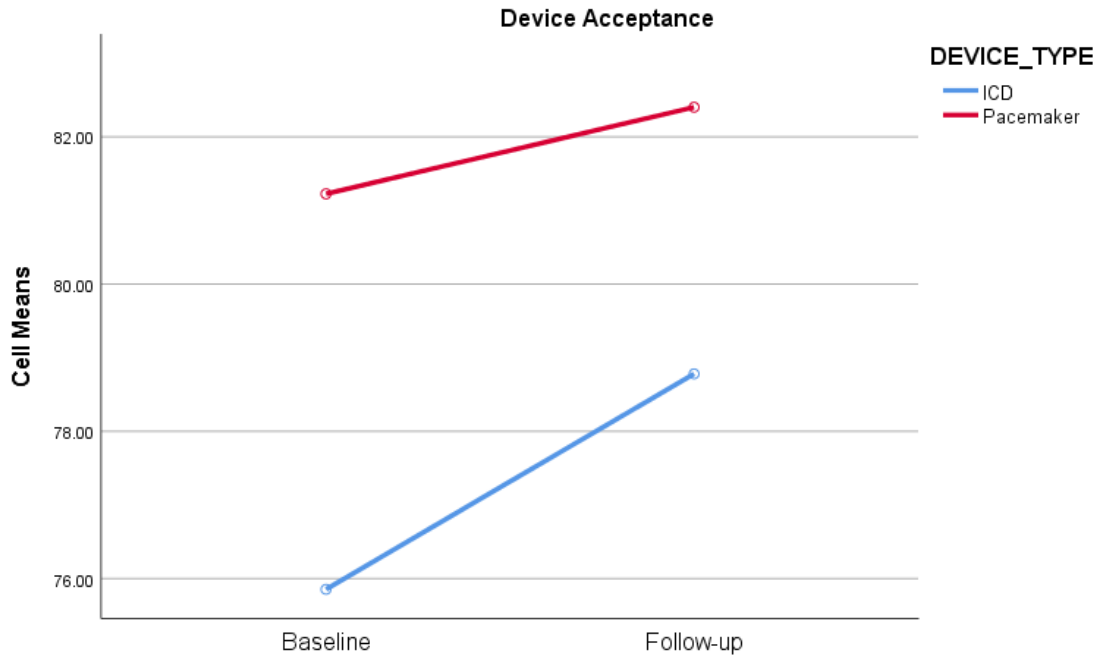

Table 4

Device Acceptance Multiple Table for ANOVA

Source	*df*	*F*	*p*	η^2	*d*
Between Subjects					
Device type	1.00	2.02	.16	.03	
Error (Device type)	1				
Within Subjects					
Time	1.00	1.89	.17	.01	-.14
Time x Device type	1.00	.34	.56	.004	
Error	73				

*** p < .05

Aim 2.

To test the hypothesis that baseline shock anxiety means were higher than follow-up shock anxiety means, a dependent samples *t*-test was performed. Prior to conducting the analysis, the data were screened for outliers by creating z scores and revealed one case above |3.29| which

was removed from the analysis. The analysis assumptions of normally distributed difference scores were examined. The means for baseline scores were positively skewed (1.47) with moderately positive kurtosis (2.62). The means for follow-up scores were also positively skewed (1.12) but kurtosis was within normal limits (.55). A log 10 transformation was used to adjust for the data. After the transformation, baseline (g_1 = .64; g_2. = -.25) and follow-up (g_1 = .62; g_2. = -.54) means satisfied the assumption.

Next a paired-samples t-test was conducted to compare if shock anxiety was lower at 12-month follow-up as compared to baseline. There was not a significant decrease in shock anxiety from baseline (M = 1.17, SD = .15) to follow up (M = 1.16, SD = .13), t (50) = .371, p = .71 with a mean decrease of .00668 which was not a significant effect (Cohen's d = .05). The results failed to reject the null hypothesis that shock anxiety scores decreased over time during remote monitoring. Means were reconverted to original means for baseline (M = 14.93; 95% CI from 13.71 to 16.26) and follow-up (M = 14.56; 95% CI from 13.39 to 15.83). These results suggest that remote monitoring does not lower shock anxiety scores over a 12-month period.

Chapter IV: Discussion

The current study examined the effects of remote monitoring in pacemaker and ICD patients on key health outcomes including device acceptance, shock anxiety, and a novel construct, health security. The results for Aim 1 indicated that health security decreased between baseline and 12-month follow-up, while device acceptance remained similar at both time points. This finding on these two measures did not differ by device type. These results do not support the hypothesis that ICD patients report lower device acceptance or health security as compared to pacemaker patients. Further, this finding is not consistent with previous literature as Bediar and colleagues (2015) who found that pacemaker patients had higher levels of device acceptance as compared to ICD patients. Similarly, Burns and colleagues (2005) found that pacemaker patients had higher device acceptance as compared to ICD patients. Conversely, other literature supports the similarity of QoL between ICD and pacemaker patients. Patient reported outcomes such as general QoL do not differ significantly by device type (Leosdottir, et al., 2006), even when the presence of ICD shocks were assessed (Duru et al., 2001). These findings may suggest that ICD patient experience is comparable to pacemaker patient experience when there is an absence of shocks, even when device specific measures of QoL are used.

Device acceptance scores, as measured by the FPAS, were similar for both pacemakers (M = 85.4) and ICDs (M = 76) to other studies (Burns et al., 2005; James et al., 2012), but these studies indicated a larger difference between pacemakers and ICDs (Bedair et al., 2015) as compared to the current study. Specifically, pacemaker patients had slightly higher scores and ICD patients had slightly lower scores as compared to the current sample. However, these studies differed on key demographic variables, including younger age patients who were younger when they received their implant. This may explain the lower scores of device acceptance for ICD

patients, as younger patients tend to have lower levels of device acceptance (Sears & Conti, 2002). Further, Bedair and colleagues (2015) controlled for cardiac diagnosis, which was not viable in the current study. Additionally, Bedair and colleagues' study had a further strength in that they created different groups based on the type of ICD. This may have influenced the results as different ICD placements and functions have been shown to have different trends overtime on device acceptance with cardiac resynchronization therapy reporting lower device acceptance at follow-up as compared to ICD patients (Ford et al., 2014).

In regard to shock anxiety within this study there was not a significant within-subjects difference on device acceptance or shock anxiety. Other studies (Udo et al., 2013) found an initial increase in QoL for newly implanted pacemaker patients at the one-year mark, followed by a gradual decline in QoL. Self-reported QoL was lower than preimplant scores by 3 years. The current study did not detect any change at the one-year follow-up. Patients in the current study had already been living with their device for 2 years on average and may have comparable scores. Additionally, given the existing literature, it is likely that patient reported QoL will continue to decrease over time due to progressive cardiac disease and advancing age.

The only significant finding for Aim 1 was that both pacemaker and ICD patients reported less health security at follow-up as compared to baseline, which is opposite of the hypothesis. The construct of health security was piloted in the current study to ascertain patient perceptions of their health to determine the extent that they consider their health is reliable and desirable in the near future. Little is known about the relationship or direction this construct has with other measures. During the study, patients reported less security in relation to their health. This finding raises an interesting issue and can be interpreted several different ways. These results suggest that the novel construct can assess unique aspects of the patient experience not

captured by device specific measures of QoL, such as the FPAS. Just as general measures of QoL may not be specific enough to detect subtle differences among device patients (Sears & Kirian, 2010), health security may assess a unique dimension of a patient's assessment of their health in the future. Additionally, patients with remote monitoring have a unique relationship with their health as their health status is constantly being monitored.

The results from Aim 2 indicate that shock anxiety remained similar during the one-year period of the study. This finding indicates that remote monitoring did not alter the patient experience of shock anxiety which did not support the hypothesis of the current study. FSAS scores were comparable to other studies (Ford et al., 2012; Tripp et al., 2019) who also found that it did not significantly differ between baseline and follow-up (Ford et al., 2014). Additionally, inspection of the data revealed a positive skew indicating that the majority of patients endorsed low levels of shock anxiety, which is in line with finding in the literature (Kuhl et al., 2006). Lastly, there were not enough participants who were shocked over the course of the study to examine differences on outcome measures.

The experience of shock has been identified as the most commonly reported predictor of shock anxiety (Tripp et al., 2019). Further, the presence of pacing and/or shock produces higher levels of shock anxiety as recorded by the FSAS (Perini et al., 2017), Within the current study, there were six shocks detected, which is consistent with literature that 4-6% of patients experience shock in a given year (Sears, Whited, & Volosin, 2015). It seems that remote monitoring did not impact shock anxiety as hypothesized and is more consistent with literature in terms of lack of change. However, in this study, there may not have been enough patients who were shocked that would shift the mean substantially.

Remote monitoring has been recommended by the FDA and Heart Rhythm Society for the treatment of heart disease (Slotwiner et al., 2015). The added monitoring of a patient's health status may alter their view of their device. Patients may feel more secure in their health outcomes knowing that the moment that a problem occurs, qualified medical professionals will be alerted. However, the added attention to one's health, especially when a person's health status has declined, may serve as a reminder of poor health status and result in negative appraisals of health. Literature regarding patient reported outcomes has suggested that RPM does not affect patient reported outcomes within two years (Versteeg et al., 2019). Even when RPM is added to usual care, patient reported outcomes such as anxiety, depression, and device acceptance did not change (Leppert et al., 2020). Yet, changes may still occur within this population that are not detected by existing measures.

Remote monitoring may be a way to provide patients with a higher level of perceived support from health professionals which may lower shock anxiety in this sample. Perceived support from healthcare professionals has been shown to moderate the relationship between device acceptance and shock anxiety (Morken et al., 2014; Wilson et al., 2013). However, the benefits from RPM may not be robust enough to alter patient reported outcomes (Leppert et al., 2020).

Scores of device related QoL, such as device acceptance and shock anxiety, remain stable overtime without intervention (Ford et al., 2014). However, this finding needs additional support for patients enrolled in remote monitoring. A meta-analysis using remote monitoring conducted by Versteeg and colleagues (2019) found no change in patient reported outcomes during the two-year study period. However, the studies in this meta-analysis differed from the current study in several keyways including duration and frequency of remote visits. Several studies lasted two

years or more and participated in remote monitoring visits on a more frequent basis such as every three months as compared the current study which had a single visit at the six months. The current study maintains the claim that remote monitoring is comparable to in-clinic visits for patient reported outcomes and is a viable treatment alternative as there were not decreases in device acceptance or increases in shock anxiety.

Lastly, the present Canadian sample may deviate from a sample in the United States in two important ways. First, the demographics of the study revealed that all participants were Caucasian which does not represent more diverse United States samples. Secondly, Canada has universal access to healthcare, making affordability of treatment a nonissue. This standard of practice is not consistent with a sample in the United States. As such, a United States sample may report lower levels of health security due to issues with coverage and affordability of health care as compared to the current sample. Individuals with more reliable health care coverage may have more access to health information. Additionally, the Canadian sample may have increased health literacy as they have more reliable health care coverage. However, these benefits may be diluted in rural patients who may have less access to health care and are not as engaged in their health care.

Limitations

This study had several limitations including limited information on the interpretation of the findings, the lack of a control group, having a device-experienced sample, a low dose of the intervention (e.g remote monitoring), high amount of missing data, and low sample size. First, limited information is known about the construct of health security and how it related to other measures. The proposed factor structure of the scale included four variables, however, only two factors were identified by a principal component analysis. Second, the current study did not have

a control group, making it difficult to ascertain the extent that RM treatment influenced the results. Third, patients in the current study had been living with their device for an average of two years and may not experience as pronounced fluctuations in their QoL as they are more accustomed to living with a device. Fourth, the current study replaced in-person visit with a remote visit. This change may not have been enough to influence patient reported outcomes. Additionally, Canada has a single payor health care system which is more accessible to patients and have influenced the results more than utilizing remote monitoring. The study may have inadvertently assessed the effect of being Canadian and having free healthcare. Fifth, the study had a low response rate that may have been indicative of response bias. Although the number of participants who did not provide data or dropped out of the study is consistent with remote monitoring literature (Varma et al., 2015), it may be indicative of response bias. Of the 176 participants, 39 participants were completely missing from the data set and did not complete any measure leaving 137 participants: 56 pacemaker and 81 ICD patients. A portion of missing data was due to participants not completing all items on measures, for example, 125 participants completed some items on the FPAS but only 112 completed the entire measure, with 107 completing all items at 12-month follow up. Lastly, the current study had a small sample size. Participants were excluded if they did not complete all the measures for baseline and follow-up. This resulted in a considerable number of patients being excluded from the analysis. This led to a reduction in sample size and statistical power.

Future directions

Future studies could address the limitations addressed above such as increased sample size, longer study duration, inclusion of more patient reported outcome measures, and include a control group for patients who did not receive remote monitoring. Future studies could seek to

assess underlying factor structure of health security and measure the construct with different samples and health conditions. Remote monitoring did not adversely impact patient reported outcomes and is more cost effective. This study can be added to the growing body of literature in support of the use for remote monitoring for cardiac conditions. This finding is germane to the current COVID-19 pandemic as it reduces risk of exposure and by limiting the number of required in-person visits.

Chapter V: Conclusion

Remote monitoring has been recommended by the Heart Rhythm Society as a viable treatment method for individuals with pacemakers and ICDs (Slotwiner et al., 2015) as evidence suggests comparable if not better, outcomes on patient mortality (Parthiban et al., 2015). The current study sought to extend emerging literature assessing patient reported outcomes as a primary end point of study. Device specific QoL, as indexed by FSAS and FPAS, remained stable during the one-year study period and did not differ significantly based on device type, however, between group differences have been noted in other studies (Bedair et al., 2015). However, the causative nature of remote monitoring on outcomes is uncertain due to the lack of a control group. Lastly, the construct of health security was piloted during this study and detected significant differences between baseline and follow-up. More research may be needed to better understand this novel construct and the insight it provides on patient QoL.

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