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Evaluation of CardioMEMS Heart Failure Device

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Abstract

Background: Heart failure (HF) is a chronic condition where the heart cannot pump enough blood to adequately oxygenate cells. The CardioMEMS HF device is implanted into the pulmonary artery (PA) allowing practitioners to monitor pressures remotely and prescribe interventions.

Objectives: The primary purpose of this project was to determine if CardioMEMS is an effective intervention in the reduction of hospital admissions, emergency department (ED), and clinic visits for HF patients. The secondary purpose was to determine if the quality of life (QOL) and exercise tolerance was improved post-implant.

Methods: The author conducted a retrospective chart review by accessing previously compiled data for patients with the CardioMEMS device to evaluate the number of hospital admissions, emergency, and clinic visits pre and post-implant. Patients completed the Minnesota Living with Heart Failure Questionnaire to determine if their QOL improved. Pre and post 6-minute walk test (6MWT) data was reviewed to evaluate exercise tolerance.

Results: The CardioMEMS HF device shows potential to decrease acute inpatient care needs and improve QOL for HF patients. Hospital admissions for HF were significantly reduced post implant ($p= 0.020$). Self-reported QOL scores significantly improved post-CardioMEMS implant ($p<0.0001$). There was a non-significant trend towards decreased ED ($p= 0.292$) and clinic visits ($p=0.438$) post-CardioMEMS implant. Comparison of changes in 6MWT was inconclusive.

Conclusion: The CardioMEMS HF device appears to be a valid option to help minimize acute care needs of HF patients while improving QOL for most. More research is needed to determine effectiveness of CardioMEMS device for exercise tolerance.

Evaluation of CardioMEMS Heart Failure Device

Problem Statement

With obesity rates rising and numerous comorbidities facing the nation, the risk for chronic conditions is at an all-time high. These chronic conditions put a strain on the healthcare system by contributing to avoidable hospital admissions, increased emergency department (ED) and clinic visits. Additionally, patient readmissions within 30 days after hospitalization further strain the healthcare system and are an indicator of the quality of patient care. The decrease in reimbursement rates that hospitals receive from the government and private insurance providers is an avoidable organizational consequence of preventable hospital readmissions.

Of six conditions that are noted for the highest hospital readmission rates, heart failure (HF) patients were more likely than any other patients to be readmitted within 30 days of discharge (Hines, Barrett, Jiang, & Steiner, 2014). According to a recent article, HF readmissions cost an average of $13,000 per case and accounted for roughly 25% of all readmissions (Hines, et al., 2014).

Beyond the straining of resources, chronic conditions can take a toll on patients' perceived quality of life (QOL). HF is a chronic condition where the heart muscle weakens making it difficult to pump oxygenated blood through the body. This leads to fatigue, shortness of breath, and difficulty performing activities of daily living (ADLs). There is no cure for HF, only symptom control with medications, weight checks, and lifestyle changes (AHA, 2017).

Purpose

The primary purpose of this project was to conduct a retrospective chart review to determine if the implantable device, CardioMEMS is an effective intervention in the reduction of hospital admissions, ED visits, and clinic visits for HF patients. To achieve this, the author

examined hospital admission, ED, and unscheduled clinic visit data before and post-implant for patients with the CardioMEMS device. The secondary purpose of this project was to determine if HF patients' perceived QOL improved after implementation of the CardioMEMS device. Patients' self-reported scores on the Minnesota Living with Heart Failure Questionnaire (MLHFQ) were obtained to measure QOL. The 6-minute walk test (6MWT), a simple measure for aerobic exercise tolerance, was conducted pre and post-CardioMEMS implant to evaluate the effectiveness of the implant for improving exercise tolerance.

Research Questions:

1. Was there a significant difference in LOS, acuity of condition, and number of hospital admissions, emergency department (ED), and clinic visits in patients diagnosed with HF before and after receiving CardioMEMS implant?
2. Was there an improvement in the HF patients' perceived QOL after receiving the CardioMEMS HF device?
3. Is there a significant increase in 6-minute walk distance in HF patients post-CardioMEMS implant compared with pre-implant?

Specific Aims

1. Perform a retrospective chart review to determine if the CardioMEMS device is an effective intervention to reduce hospital admissions, acuity of the condition, length of stay, ED visits, and clinic visits for HF patients.
2. Administer the MLHFQ to determine if the CardioMEMS HF device has improved the perceived QOL after obtaining the implant.
3. Compare existing 6MWT data pre and post-CardioMEMS implant to determine if there is an improvement in exercise tolerance.

Background

HF is a chronic, progressive condition where the heart muscle is unable to pump enough blood through the body to adequately oxygenate cells, leading to shortness of breath, fatigue, and at times, coughing. Currently, there is no cure for HF with the only option to control symptoms by using medication and lifestyle changes (AHA, 2017).

According to the American Heart Association (AHA), the prevalence of HF in America is on the rise with approximately 900,000 new diagnoses each year. As of 2014, 6.5 million people were living with HF compared with 5.7 million people just two years prior. HF is the leading cause of hospitalization in adults over 65 years of age (AHA, 2017). In 2014, the prevalence of HF in Medicare patients was 11%, yet 34% of all Medicare/Medicaid healthcare cost can be attributed to HF patients, while 42% of Medicare admissions are for HF (Fitch, Pelizzari, & Pyenson, 2015). HF patients account for 55% of all hospital readmissions and cost three times as much as other diagnoses (Fitch, et al., 2015).

Another factor to consider is the impact HF admissions have on hospitals across the country. With the implementation of the Affordable Care Act (ACA) in 2010, hospitals are facing financial penalties for 30-day hospital readmissions (Kripalani, Theobald, Anctil, & Vasilevskis, 2014). With readmission penalties reaching an all-time high, 2014 estimates put the total amount that Medicare will withhold at more than half a billion dollars and providers are struggling to reduce hospital readmission rates (Kripalani, et al., 2014). Reducing avoidable readmissions is also a key goal for the Centers for Medicare & Medicaid (CMS). Patients under active readmission prevention programs are more likely to have an improved functional status and QOL (Sheingold, Zuckerman, & Shartzer, 2016).

Failure to successfully transition patients from inpatient to outpatient care results in readmission to the hospital. When this failure occurs, it is a violation of the Institute for Health Improvement's (IHI) Triple Aim initiative. According to the article by Hitch et al. (2016), the IHI's Triple Aim is to improve the quality of care, improve the health of populations, and reduce cost. Healthcare systems that have a high percentage of patients with 30-day hospital readmissions, neglect to improve the quality of care, improve the health of populations, and reduce costs (Hitch et al., 2016).

It is beneficial to reduce hospital admissions, along with ED, and clinic visits to improve overall health and QOL for HF patients. CardioMEMS, a device developed by Abbott, is an intervention that may improve HF patient outcomes (Abraham et al., 2011). CardioMEMS is an implantable device that allows practitioners to remotely monitor the pulmonary artery (PA) pressure of HF patients. The device is inserted during a standard right heart catheterization as part of an outpatient procedure by accessing the femoral artery using a sheath, with the CardioMEMS inserted over a guide wire, and finally deployed in the pulmonary artery.

Literature Review

The author conducted a review of the literature to evaluate the use of the CardioMEMS HF implantable device related to decreased hospitalizations, ED, and clinic visits, in addition to improved QOL and exercise tolerance. The CardioMEMS device is an intervention that was approved by the Food and Drug Administration (FDA) to monitor the pulmonary artery (PA) pressure of select HF patients. The wireless implant transmits data to a secure database that allows clinic and medical professionals to view and interpret the patient's PA pressures. Data sent from the device to clinics providing follow up care to patients with the device allows for

implementation of proactive measures to keep HF patients out of the hospital and emergency departments, as well as reduce clinic visits (St. Jude Medical, 2016).

Several studies have evaluated the effect of CardioMEMS on hospital readmission rates in HF patients. The landmark CHAMPION study, the first of its kind, monitored CardioMEMS recipients from 2005 to 2011 (Abraham et al., 2011). The purpose of the study was to determine the long term-safety and efficacy of the CardioMEMS HF device. The authors achieved this by following 550 HF patients that received the CardioMEMS implant in comparison with 120 control patients without the device from 64 sites across the United States.

Abraham et al. (2011) recognized that despite current treatments and interventions, admission rates for HF patients have remained unchanged. Many patients admitted to the hospital with congestive heart failure (CHF) exacerbation could benefit from earlier detection. This congestion results in elevated pulmonary artery (PA) pressures. The CardioMEMS is an implantable device that monitors patients' PA pressures, which elevates weeks before hospitalization is necessary. The CardioMEMS device sends PA pressures remotely to clinics so that closer monitoring of HF patients can take place. The study found that there was a reduction of 37% of hospital readmissions in the treatment group versus the control group. The limitation listed for this study was the challenge of potentially unmasking patients. According to the authors, the research was funded by CardioMEMS (Abraham, et al., 2011).

Similarly, Davidovich et al. (2017) performed a retrospective chart review of 119 patients with the CardioMEMS HF device from four different hospital sites in Minnesota and South Dakota to determine if CardioMEMS HF device was an effective intervention to decrease hospital admissions. The researchers retrospectively reviewed charts from a cohort of 119 HF patients who received the CardioMEMS implant and concluded that emergency room visits and

hospitalizations were reduced in HF patients that had CardioMEMS. The study showed a post-CardioMEMS implant decrease in HF hospital admissions from 187 to 36 and ED visits for HF from 1110 to 616 in the first year post-implant (Davidovich, et al., 2017).

Additionally, Kanat and Nichols (2017) performed an analysis of 34 HF patients with CardioMEMS implants at a hospital in Northern California to determine the effectiveness of CardioMEMS in reducing healthcare utilization and hospital admission rates. This retrospective chart review examined the medical records of 34 patients with CardioMEMS implant for the 12 months before and after the device was implanted. The data revealed that 17 of the 34 patients with the CardioMEMS FH device had no hospital admissions in the year post-implant compared to pre-implant data of 69 total hospital visits. This data helped the authors to conclude that the CardioMEMS HF device has a positive impact on hospital admission rates for HF patients that have received the CardioMEMS device. The authors neglected to discuss limitations, conflict of interest, or funding information in their research paper (Kanat & Nichols, 2017).

To further add to the evidence, Ratham, Unruh, Nissley, Nissley, and Roberts (2016) conducted a post-implant retrospective review of 21 patients with CardioMEMS implants between February 2015 and October 2015 to evaluate HF related hospital admissions. The researcher found on average hospital admissions reduced from two to 0.6 per year for patients with the implant. They also concluded that CardioMEMS is the first HF diagnostic tool to positively impact hospitalizations in HF patients with preserved ejection fraction. There were no limitations, conflict of interest declaration, or information about how the study was funded (Ratham, et al., 2016).

To evaluate the actual physiological impact, Heywood et al. (2017) reviewed CardioMEMS data of 2000 patients with the device from all over the United States. Data was

collected directly from St. Jude Medical database. The database is a patient care network where device driven data is managed and stored. The purpose of this database is to allow caregivers to view data from devices such as the CardioMEMS HF device and pacemakers in order to make clinical decisions (St. Jude Medical, 2018). The researchers' purpose was to establish a data review separate from previously conducted clinical trials. They found through a retrospective chart review that patients with CardioMEMS had significantly lower PA pressure after the device was implanted versus before implantation, which lead to fewer HF exacerbations needing intervention (Heywood, et al., 2017).

The CardioMEMS HF device has been shown to be a cost-effective way to manage HF patients. By utilizing a Markov model, a way to predict or forecast future events, Schmier, Ong, and Fonarow (2017), were able to determine the cost-effectiveness for the CardioMEMS device versus the current standard of care. The model compared outcome data over five years for those with CardioMEMS HF device versus the current standard of care for patients with HF. The study included the cost of having the device implanted, cost of monitoring the patient and of subsequent hospitalizations for HF. The authors concluded that the CardioMEMS device improved quality-adjusted life year (QALY) over the standard of care thus demonstrating the device cost effective (Schmier, et al., 2017).

Overall, the literature supported the use of CardioMEMS in HF patients to help manage HF symptoms and exacerbations. Most of the articles reviewed had small sample sizes because the CardioMEMS HF device received FDA approval in May of 2014 meaning the pool of recipients is rather small. Several articles also neglected to include limitations, conflict of interest declarations, and how the research was funded. All the articles showed a decrease in the number of hospital admissions for HF patients with the CardioMEMS device. What is not clear

from conducting the literature review is if CardioMEMS HF device leads to an improved QOL and better daily functionality and exercise tolerance. With this study, the author hoped to add a better understanding of how the CardioMEMS device improves both QOL and exercise tolerance while keeping HF patients out of the hospital and ED.

Significance

Evaluation of the CardioMEMS data collected on HF patients that receive care at the Heart and Vascular Clinic was conducted to reveal whether or not the device contributed to decreased hospitalizations, ED visits, and clinic visits in this sample. Few studies have evaluated QOL and 6MWT in patients after receiving the CardioMEMS implant. The MLHFQ questionnaires were given to the HF patients at Heart and Vascular Clinic to determine if there were differences in the perceived QOL for HF patients with the CardioMEMS device pre and post-implant. Data obtained from 6MWT completed at the clinic both pre and post-implant were also conducted to reveal if having the CardioMEMS device improved exercise tolerance. The data analyzed in this project may help clinicians understand if the CardioMEMS device reduces hospitalization and improves exercise tolerance and overall QOL of HF patients.

The medical center has trialed several programs for HF patients in the past to reduce hospital admission rates for HF patients with little success. These interventions include discharge follow-up calls to HF patients, providing resources such as scales and logs for tracking daily weights, medications and blood pressures. This project intended to determine if there is a significant decrease in hospitalization, ED, and clinic visits in HF patients with the CardioMEMS device. Findings from this project may identify a viable intervention to help hospitals reduce cost and increase reimbursement rates by keeping HF patients out of the

hospital. Reaching out to patients with CardioMEMS HF device can identify potential issues, patients can be referred to their primary care provider, and prevent admission to the hospital.

Gaps in Knowledge

At the time the research was conducted, heart and vascular clinic did not know if the CardioMEMS HF device has any impact on decreasing hospital admissions, ED, or clinic visits or if it improves the QOL for HF patients. The heart and vascular clinic along with the medical center had been collecting data on HF patients that have the CardioMEMS device, but analysis of the data had yet to occur making it impossible to determine the effectiveness of the device. This research study extracted and examined data so that it could be determined if the CardioMEMS device reduces hospitalizations and improves the QOL of those that have received the implant. Findings from this project helped to determine if the intervention is useful for improving HF patient outcomes.

If the CardioMEMS device proves to be effective in reducing hospital admissions, ED visits, and clinic visits for HF patients, it could be an essential cost-saving intervention. At the time the research was conducted, the medical center had placed the CardioMEMS implantable device in 19 patients, but the data had not been analyzed to determine if this was a useful intervention for HF patients.

Theoretical Foundation

The theoretical framework that supported this project is the Analyze, Design, Develop, Implement, and Evaluate (ADDIE) model. This model was an instructional design that helped formulate solutions to a given problem through a five-step process, including an in-depth Analysis, Design, Development, Implementation, and Evaluation of the research questions and overall project (McGriff, 2000). The ADDIE model was particularly useful when applied to this

research project, as data analysis is the key to determine the next step in the process. This model was a valuable tool for planning, implementation, and evaluation of this research project (See appendix for ADDIE diagram).

The author applied ADDIE to the research questions to help guide the analysis and evaluation of CardioMEMS implants in HF patients and its impact on the patients that have received the device. During the design and development phase, the author made decisions regarding what the study design was going to be and developed the research questions and how best to obtain answers. After receiving IRB approval, implementation of the study began which consisted of gaining a waiver of consent from patients and administering the MLHFQ. This model also assisted in keeping the research on track by referring to the steps at different stages of the proposal development. During all phases, evaluation takes place, formative while the research study is ongoing and a cumulative evaluation occurred at the end of the study to provide the conclusion and recommendations.

Variables

Defining the dependent, independent, confounding and clinical variables was a crucial step to help examine all the factors that contribute to whether the CardioMEMS device was an effective intervention to reduce the number of times that patients with HF seek care (See Table 1). The dependent variables were hospital admissions, acuity of the condition, length of stay, ED visits, clinic visits for HF exacerbation, MLHFQ, and 6MWT. The author conducted a retrospective review of patient data to determine the precise number of patients with the CardioMEMS device admitted to the hospital or who sought care for HF complication one year prior and one-year post-implant. The MLHFQ was collected retrospectively due to the Clinic not conducting this questionnaire before device deployment.

The independent variable is the CardioMEMS implantable device. It was necessary to include diagnosis date, date of CardioMEMS implant and the number of hospital admissions, ED, and clinic visits one-year prior and one-year post-implant for HF complications.

The confounding variables affected hospitalizations and reasons for seeking care for complications of HF. The author documented what interventions if any, the provider prescribed to help keep patients out of the hospital or from obtaining care in the ED or clinic. Two other clinical factors that could influence how well a patient did post-discharge include the hospitalization admit diagnosis, comorbidities, and the acuity of the patient. The author collected demographic data as well, including age, race, gender and marital status.

Research Design

The author utilized a retrospective chart review to determine if CardioMEMS was an effective intervention for decreasing the frequency of, length of stay, and acuity of hospital admissions, ED, and clinic visits for HF-related symptoms or conditions. The data reviewed spanned one year prior and one-year post-implant that the Medical Center and the Heart and Vascular Clinic collected during the normal day-to-day operations. A pre and post-study design was used to determine if the self-reported QOL for patients with the CardioMEMS implant improved post-procedure by collecting the MLHFQ. The author also conducted a review of the 6MWT data collected by the heart and vascular clinic pre and post-implant.

Study Population

The target population for this project was HF patients with the CardioMEMS implant. The available sample was HF patients at a tertiary care center in the Pacific Northwest and the heart and vascular clinic operated by the medical center, who received the CardioMEMS implant. This author contacted the patients that have the CardioMEMS device and receive

follow-up care at the heart and vascular clinic via telephone to obtain consent to participate in the study. After a brief introduction, the author administered two MLFHQ. The patients were able to participate in the study by answering both questionnaires, reflecting how they rate their QOL pre and post-CardioMEMS implant. Inclusion criteria were as follows; participants must have the CardioMEMS device and receive outpatient care at the heart and vascular clinic and inpatient care from the medical center, and consent to be included in the study. Excluded cases included all patients that have not received the CardioMEMS implant or are no longer receiving care at the heart and vascular clinic, those who declined to participate, patients that the author was unable to reach via telephone, or those that were deceased.

Sample Size

At the time this research was conducted 19 patients were participating in the CardioMEMS program and receiving follow-up care at the heart and vascular clinic. Of the 19 patients, 18 qualified to participate in this research study. The author was able to obtain consent for chart review and complete 14 MLHFQ surveys of the 18 eligible patients.

Setting

This study took place in a community-based, not-for-profit, tertiary care facility that consists of four separate hospitals that care for HF patients. In 2012 the medical center, affiliated with another larger hospital system to become one of the largest healthcare providers in the Pacific Northwest and Alaska. At the time of writing this report, the medical center remained a distinct entity responsible for the day-to-day operations including human resource affairs and separate union representation. The two organizations share the same financial and patient outcome goals. Patients included in the study all received follow-up care at the heart and vascular clinic operated by the medical center.

Intervention

CardioMEMS is an implantable, hemodynamic monitoring device manufactured by St. Jude Medical Inc. The manufacturer's data show that the device reduces hospital admissions for HF patients (St. Jude Medical, 2016). An interventional cardiologist inserts the CardioMEMS HF device into the pulmonary artery (PA) during a standard right heart catheterization. After deployment of the device, it begins sending PA pressures to a secure server. The device sends alerts to the provider if the set PA mean trends higher for three consecutive days. Once alerted, the provider can contact the patient with interventions, such as adjusting medication or fluid restrictions to help reach the ideal PA meanwhile avoiding hospitalization and Emergency Room visits (St. Jude Medical, 2016).

Measuring Variables and Operational Definition

The independent variable is having the CardioMEMS HF device implanted. The dependent variables include perceived QOL, exercise tolerance, admission to the hospital, ED visits, and clinic visits for HF symptoms or exacerbation. The author defined the confounding, covariant, and clinical variables and listed them in the variable table in the appendix. See table one in the appendix for a complete list of variables.

Measurement Tools

Exercise tolerance was measured using the 6MWT. Bellet, Adams, and Morris, 2012, conducted an extensive literature review to determine if the 6MWT was a reliable and valid tool to assess exercise tolerance in cardiac patients. The authors concluded that the literature review found the 6MWT demonstrated strong test–retest reliability (intra-class correlation coefficient = 0.97) between repeated 6MWT. As for the validity, the authors were unable to determine due to limited research and literature available (Bellet, et al., 2012).

Uszko-Lencer et al. (2017) conducted a retrospective observational study to determine if 6MWT was reliable and valid as a prognostic tool for HF patients. The 6MWT is a valuable tool for many conditions to assess daily functionality. The test consists of the patient walking on a hard, flat surface for six minutes or as long as tolerated, whichever comes first. The authors determined that the distance traveled in that time can be a predictor of mortality and increased risk of hospitalizations. The researchers concluded that 6MWT is a reliable and valid tool to measure daily functionality (Uszko-Lencer, et al., 2017).

Uszko-Lencer et al. (2017) determined the 6MWT was reliable (ICC = 0.90, $P < 0.0001$). The learning effect was 31 m (95%CI 27, 35 m). To test the reliability of 6MWT, the two-way random intra-class correlation coefficient with single measures (ICC2, 1) was calculated. The paired t-test was used to test differences between two 6MWT. The unpaired t-test, one-way ANOVA, or chi-square was used to compare groups. The authors determined that the 6MWT was reliable and valid in patients with mild-to-moderate HF (Uszko-Lencer et al., 2017).

The MLHFQ was used to measure patient's self-reported QOL. Mogel, Buck, Zambroski, Alvaro, and Vellone (2016) conducted a cross-sectional study to determine if the MLHFQ showed cultural bias. The authors concluded that some questions on the survey might vary depending on the geographical location, but it does not affect the validity of the questionnaire. Cultural influences are often at play. Researchers should acknowledge these influencers when utilizing the MLHFQ (Mogel, et al., 2016).

The questionnaire consists of 21 questions addressing the physical, emotional, and socioeconomic aspect of HF. Questions are scored zero through five, with zero being no impact and five which very much affects QOL. The score range is 0-105. To determine the impact of the score Behlouli, et al., 2009, assigned a numeric range to determine HF patients as having

good, moderate or poor QOL. A total score of < 24 on the MLHFQ denotes a good QOL, a score between 24 and 45 signifies a moderate QOL, and a score > 45 represents a poor QOL. The authors found that these ranges correlated with survival rates, self-perceived health status, New York Health Association (NYHA) functional class, and 6MWT (Behlouli, et al., 2009).

Supino et al., 2009, determined the reliability and validity of the MLHFQ by conducting the questionnaire with 47 valve replacement patients. The authors found the Cronbach's α was ≥0.9 (total score, dimensions), supporting internal reliability was high for the MLHFQ. The secondary analysis confirmed the MLHFQ for physical/emotional domain items (relative chi-squares <3.0, critical ratios >2.0, both instruments), supporting structural validity. Spearman coefficients correlating MLHFQ with parallel SF-36 domains were moderate to high (0.6-0.9; P ≤ .001: T 0 -T 2), supporting convergent validity (Supino et al., 2009).

Data Collection

This project utilized previously collected data through a retrospective chart review of HF patients that have the CardioMEMS device. Data extraction included hospitalizations, for patients that were admitted to the hospital with a diagnosis or complication related to HF, ED visits, and clinic visits, as well as, demographic variables. The author reviewed data from records at both the Heart and Vascular Clinic and all inpatient facilities within the organization. Given that the organization managed the data, it helped ensure that the author was reviewing up-to-date and accurate information.

Another way to substantiate this claim was that the organization is responsible for collecting and submitting accurate data to the Center for Medicare and Medicaid to be compliant with the laws put forth by the Affordable Care Act. Data collection and management adhered to the standards set forth by the organization and were in compliance with HIPAA laws. As

previously stated, the data was accessible via the EMR. Protecting patients' identities was of utmost importance. The author ensured confidentiality by assigning each patient subject numbers as identifiers; no names were available in this format.

To complete the MLHFQ with patients that received the CardioMEMS implant, the author called each patient via telephone. The author used a recruitment script to inform patients as to the nature of the study, voluntary participation, and to ensure each patient that maintaining their confidentiality was a priority. The 6MWT was completed in the clinic both pre and post-implant and was available as previously collected data. The author utilized a retrospective chart review to collect the data with the exception of the MLHFQ questionnaire.

Timeline

A Gantt chart was constructed to show the timeline for this study. This chart helped the author stay on track and focus on the next steps of the paper. SPSS 23 software and Microsoft Excel spreadsheets were used to store, organize, and manage the compiled data. A copy of the Gantt chart is in the appendix of this paper.

Data Analysis Plan

This project consisted of a retrospective chart review along with questionnaires administered to patients with the CardioMEMS HF implant to determine if the device is an effective intervention to improve QOL and reduce hospital admissions, ED visits, and clinic visits for patients diagnosed with HF. The author analyzed data that was collected previously by the organization's quality department and maintained in the patient’s electronic medical record. To determine if there were patterns to the data the author reviewed frequency tables according to descriptive variables such as age, sex, and diagnosis. To establish whether there was statistical significance, a paired sample t-test was conducted to compare if there was a significant

difference in the number of ED visits, hospitalizations, and clinic visits pre and post-CardioMEMS HF device implantation.

To determine if CardioMEMS HF device improved the QOL for its recipients the author administered the MLHFQ to patients with the CardioMEMS device that sought care at the Heart and Vascular Clinic. The recipients completed two questionnaires, recalling their QOL pre-implant and also reflecting on how they feel post-implant. The author then conducted a paired samples t-test to determine if there is a significant difference in self-reported perceived QOL before and after CardioMEMS implant.

With the questionnaires being subjective, it was important to look objectively at whether patients have improved exercise tolerance pre and post-implant. The author reviewed the 6MWT data that the Heart and Vascular Clinic collected pre and post-CardioMEMS implant to determine objectively whether the patient's exercise tolerance had improved. Again, the author conducted a paired sample t-test to determine if these patients had improved exercise tolerance after the CardioMEMS implant.

After compiling the dataset, relevant statistics such as the mean, standard deviation, and range for continuous variables and descriptive statistics such as percentages and frequencies for categorical variables were generated. Due to the small sample size, the author utilized descriptive statistics to identify trends. After examining the data, the author decided a paired t-test was warranted. Assuming an effect size of 0.70 (Cohen's d), a power of 75% (0.75), and a type 1 error rate (alpha) of 0.05, 14 participants were required to conduct a paired samples t-test with a one-tailed test of significance (Plichta, 2013).

Ethical Considerations

To comply with Institutional Review Board (IRB) standards and the guidelines put forth by the Health Insurance Portability and Accountability Act (HIPAA), protection of patient identities is of utmost importance. As stated above, the author ensured confidentiality by using unique subject numbers as identifiers rather than names and age range instead of specific birthdays. The author entered and stored all information into approved hospital software and saved it on a USB drive inspected and permitted by the organization. The author ensured active firewalls and encryption along with password protection to help keep data secure and reduce the vulnerability of the system. The author maintained transparency by operating within the IRB approval and seeking an amendment when changes or corrections became necessary. Only the researchers approved by the IRB had access to the data compiled for this study. Both the Medical Center and the George Washington University IRB reviewed and approved the study.

Results

Demographics. After collecting the retrospective chart review data and completing the MLHFQ the author compiled the data into the codebook. Next, the data was entered into the SPSS software developed by IBM to examine descriptive statistics and determine if the results were statistically significant. Descriptive characteristics for the participants according to age, gender, race, marital status, alcohol, tobacco and drug use are presented in Table 2. The demographic breakdown for patients included in this study was collected to help identify trends if they exist. The study included ten males and four females. Five patients are Black and nine are Caucasian. Five patients are married and nine are single. Of the 14 patients, one is between the ages of 50-59, five are 60-69, seven are 70-79, and one is 80-89.

Lifestyle choices. Along with demographic information, the author obtained a history and current use of tobacco containing products, substance abuse, and alcohol use through the chart review process. None of the patients identified as currently using tobacco products, however, eight patients are former smokers. Two patients responded that they use recreational marijuana, as it is legal in Washington State. Four patients drink one to two servings of alcohol per week.

Hospital admissions, ER, and clinic visit data. To answer the research question, was there a significant difference in the number of hospital admissions, ER, and clinic visits in patients diagnosed with HF before and after receiving CardioMEMS implant, the author conducted a retrospective chart review. Of 14 patients in the study, two patients had the same number of hospital admissions post-CardioMEMS implant versus pre-implant while two patients had more hospital admissions. Three patients had more ER visits post-CardioMEMS when compared to pre-implant data, with seven patients having the same number of visits both pre and post-implant. Two patients had increased clinic visits for HF post-CardioMEMS implant versus pre-implant, with three patients demonstrating the same number both pre and post-implant. Please see figure 1 in the appendix to see a comparison of the patient outcomes before and after CardioMEMS implant.

Statistical analysis. Analysis of the data using a paired t-test showed that the mean number of hospital admissions for HF related causes or symptoms was significantly reduced after the CardioMEMS implant compared with pre-implant hospitalizations ($p= 0.020$). There were 25 total hospital admissions pre-implant versus nine post-implant for the sample of participants. There was not a significant difference between the pre and post mean number of ED visits ($p= 0.292$), however there was a trend in the data that supports a decrease in the total

number of ED visits post-implant. There were a total of 11 ED visits pre-implant versus six post-implant for HF related causes or symptoms among the patients in the sample. The mean number of pre and post-implant clinic visits were also not significantly different (p=.438), but again, the trend in the data suggests fewer clinic visits post-implant. There were a total of 96 clinic visits related to HF causes or symptoms pre-implant versus 70 post-implant for the patients in this sample. Table 3 in the appendix shows the means, standard deviations and paired t-test results for pre and post CardioMEMS implant hospital admissions, ED visits, unplanned clinic visits and MLHFQ scores.

Comorbidities. To gain a complete understanding of the potential impact that the CardioMEMS HF device could have on patients living with HF, it was essential to consider what and how many comorbidities each patient had in addition to HF. The patients included in this study all had at least one comorbidity with ten comorbidities being the most. See Table 4 in the appendix for a detailed list of comorbidities and the number of patients effected.

Interventions. Another consideration is what interventions were prescribed by the clinic in order to maintain acceptable PA wedge pressures. Interventions ranged from adding, increasing, and decreasing diuretics, having patients go to the clinic for IV diuretics, and increasing weight checks. Of note, three patients required no intervention in the year that proceeded the device deployment. Four patients had hospital admissions for HF symptoms and exacerbation. All patients' acuity level was determined to be fair. Length of stay (LOS) for each admission ranged from one to seven days.

MLFHQ data and statistical analysis. The next research question, was there an improvement in the HF patients' perceived QOL after receiving the CardioMEMS HF device, required the author to contact patients via telephone to conduct the MLHFQ. At the point of

contact, verbal consent was obtained for the chart review portion of the study. Of the 18 eligible patients, 14 gave consent for chart review, and 13 were able to complete the questionnaire. The results of the MLHFQ showed that two patients had no reported change in QOL pre-implant versus post-implant, while 11 reported a positive change in QOL after receiving the CardioMEMS HF device. Please see figure 2 in the appendix for the graph of the MLHFQ results. A paired t-test demonstrated that overall, the mean MLHFQ scores were significantly improved for patients after receiving the CardioMEMS implant ($p<0.0001$). See Table 3 in the appendix for the paired t-test results.

6MWT data and statistical analysis. The final research question, is there a significant increase in 6-minute walk distance in HF patients post-CardioMEMS implant compared with pre-implant, required the author to review patients charts to determine if the CardioMEMS device improved exercise tolerance in HF patients. The chart review showed that of the 14 patients only three had both pre and post-walk distances recorded, while the remaining 11 only stated that the 6MWT was complete. Because of this, the author was unable to determine whether the CardioMEMS HF device improves exercise tolerance in HF patients.

Discussion

The purpose of this study was to determine if the CardioMEMS HF device decreased the acute need for patients to seek care for HF symptoms or conditions while improving the QOL and exercise tolerance of HF patients that received the CardioMEMS device. The study took place at a tertiary care center in the Pacific Northwest and the heart and vascular clinic operated by the medical center. The program included 19 patients of which 18 were eligible to participate in the study. The author was able to make contact with, obtain verbal consent from 14 patients, and complete 13 MHLQ surveys.

The data collected from the chart review and MLHFQ was entered into a codebook for further analysis. The paired t-test showed that the average number of hospital admissions were significantly decreased after receiving the CardioMEMS implant. The decrease in admissions could be attributed to early intervention when wedge PA pressures rise. The findings of this study correlate with the literature reviewed, which found less frequent hospitalization for HF symptoms or exacerbation post-CardioMEMS implant (Abraham, et al., 2011; Davidovich, et al., 2017; Kanat & Nichols, 2017; Ratham, et al., 2016; & Schimer, et al., 2017).

Largely, the results of this analysis found no significant differences in ED visits pre and post implant, but did show a trend towards reduced ED visits. The author was unable to find literature that compared ER visits pre and post-CardioMEMS implant.

Overall there were no significant differences in the mean number of clinic visits before and after CardioMEMS implant, but there was a trend towards fewer visits. When comparing clinic visits for HF pre and post-CardioMEMS implant, the author noted that one patient had significantly more clinic visits post-implant. Upon further chart review, it was determined that the patient had moved to the area shortly before the CardioMEMS was implanted, this could explain why the patient had thirteen more clinic visits post-implant versus pre-implant. Three patients had the same number of clinic visits pre and post-implant. Nine patients had fewer clinic visits post-CardioMEMS implant versus pre-implant. The group of patients that had fewer clinic visits post-implant had a mean of three, a median of two, and mode of one. The author was unable to find literature that compared clinic visits pre and post-CardioMEMS implant.

The author conducted the MLHFQ via telephone with 13 of the 18 eligible HF patients that received the CardioMEMS HF device ($p= 0.292$). Of the 13 patients, two reported no change, while 12 reported a positive change in their perceived QOL. Four of the patients

reported only moderate improvement in QOL post-implant. Those that perceived a change in QOL from poor pre-implant to good post-implant consisted of four patients. The remaining three patients stated a change in QOL from moderate pre-implant to good post-implant. One participant was unable to answer the questionnaire due to a time constraint on their end but did give the author permission to conduct the chart review. The author was unable to find any literature that compared perceived QOL ratings for patients pre and post-CardioMEMS implant and to the author's knowledge this is the first study to use the MLHFQ to evaluate the effectiveness of the CardioMEMS implant to improve QOL.

Unfortunately, the results of the 6MWT comparison from the pre-CardioMEMS implant to post were inconclusive due to documentation inconsistencies at the clinic. Of the 14 patients, three had both pre and post-implant results. Two were unchanged, and one patient was able to tolerate an additional 10 meters when comparing times pre and post-implant. The author was unable to find literature that compared 6MWT pre and post-CardioMEMS implant.

After reviewing the data, the author has determined that the CardioMEMS HF device shows potential to decrease the acute care needs and improve the perceived QOL of HF patients. Further research is needed to understand the impact that the CardioMEMS device has on exercise tolerance. Studies that include larger patient samples will be necessary to corroborate the findings of this research study.

Limitations

One limitation of this study is interpreting results due to the small study size. The number of CardioMEMS patients eligible for the study was 18. Fourteen patients agreed to participate which is a small sample and the statistical power of the study could be improved with a larger sample.

Another limitation is the MLHFQ that was administered to patients required them to give self-reported, retrospective opinions on their QOL. This could influence the study by participants giving false, misleading, or incomplete answers. Also, the author read the questions aloud to participants and unintentional biases such as inflection or emphasize on certain words could influence the participant to respond to the questions.

It is important to consider that due to the comorbidities of several patients it was difficult for them to speak directly to HF as the cause for decreased QOL. Some patients were unable to participate in the 6MWT due to physical limitations caused by factors including but not limited to HF such as chronic anemia, back, and sciatica pain.

The 6MWT data was not documented for all patients before and post-CardioMEMS HF device implant. For this reason, the author is unable to determine whether there was a significant increase in 6-minute walk distance in HF patients post-CardioMEMS implant compared with pre-implant. Not having the data is an unfortunate situation as it is an important metric to determine exercise tolerance.

Lastly, due to a few patients joining the clinic practice shortly before the CardioMEMS implant, data for hospital admissions, ER, and clinic visits does not allow for a complete clinical picture. Not having this data could skew the results to show that the devices do not appear as useful for two of the patients.

Implications/Recommendations

The implications for practice is that the CardioMEMS HF device is useful for monitoring and earlier intervention that has the potential to decrease acute care needs in patients with HF, this in turn, can lead to fewer hospital admissions, ER, and clinic visits. For healthcare

organizations this could have an enormous impact that frees up resources and perhaps capital as the need for readmission is no longer a factor.

Patients included in this research study reported either no difference or a positive change in their perceived QOL. Healthcare continues to move toward preventative medicine and for patients already dealing with a chronic condition such as HF the use of technology to help prevent more healthcare encounters can be life-changing. The CardioMEMS HF device has the potential to positively impact the QOL of HF patients. More research is needed with a larger sample size to determine if the CardioMEMS device is indeed a useful tool to decrease acute healthcare needs, improve QOL, and improve exercise tolerance.

Conclusion

In conclusion, the CardioMEMS device shows potential to decrease the acute care needs for HF patients. MLHFQ results also revealed the possibility of improving QOL. Unfortunately, the results of the exercise tolerance test were inconclusive as the chart review revealed all but three patients did not have a distance recorded, just a note that read the 6MWT was complete.

Further research may determine the exact impact on acute care needs, QOL, and 6MWT. This study served to start the discussion and to find what could be done to manage HF patients more proactively. The CardioMEMS device appears to be a valid option for those patients that demonstrate reliability and comply with any necessary interventions prescribed by the care team from the clinic.

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Appendix

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	**No**				**Very Little**	**Very Much**
1. Causing swelling in your ankles or legs?	0	1	2	3	4	5
2. Making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. Making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. Making your working around the house or yard difficult?	0	1	2	3	4	5
5. Making your going places away from home difficult?	0	1	2	3	4	5
6. Making your sleeping well at night difficult?	0	1	2	3	4	5
7. Making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. Making your working to earn a living difficult?	0	1	2	3	4	5
9. Making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. Making your sexual activities difficult?	0	1	2	3	4	5
11. Making you eat less of the foods you like?	0	1	2	3	4	5
12. Making you short of breath?	0	1	2	3	4	5
13. Making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. Making you stay in a hospital?	0	1	2	3	4	5
15. Costing you money for medical care?	0	1	2	3	4	5
16. Giving you side effects from treatments?	0	1	2	3	4	5
17. Making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. Making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. Making you worry?	0	1	2	3	4	5
20. Making it difficult for you to concentrate or remember things?	0	1	2	3	4	5

Table 1. Variable list

Variable	Theoretical Definition	Operational Definition	Measurement Tool/Data Collection Methodology
Dependent Variable Admissions to the hospital	Admitted to the hospital for symptoms or conditions related to HF.	Yes = 1 No=0	Chart audits
Dependent Variable ED visits	ED visits for symptoms or conditions related to HF.	Yes=1 No=0	Chart audits
Dependent Variable Clinic visits	Clinic visits for symptoms or conditions related to HF.	Yes=1 No=0	Chart audits
Dependent Variable MLHFQ completion	Completed questionnaires.	Yes=1 No=0	Tool: MLHFQ Phone calls to patient by this author.
Dependent Variable QOL pre-implant	What was the total self-reported QOL score pre CardioMEMS implant?	Pre-implant score=Total score on MLHFQ	Tool: MLHFQ Phone calls to patient by this author.
Dependent Variable QOL post-implant	What was the total self-reported QOL score post-CardioMEMS implant?	Post-implant score=Total score on MLHFQ	Tool: MLHFQ Phone calls to patient by this author.
Dependent Variable 6MWT improvement	Was there an improvement in exercise tolerance?	Yes=1 No=0	Tool: 6MWT Chart audit
Dependent Variable 6MWT pre implant	What was the distance the patient can walk in 6 minutes pre implant?	Pre-implant 6MWT= Total distance walked in meters and centimeters in 6 minutes.	Chart audit
Dependent Variable 6MWT post-implant	What was the distance the patient can walk in 6 minutes post-implant?	Post-implant 6MWT= Total distance walked in meters and centimeters in 6 minutes	Chart audit

Independent variable CardioMEMS implant	Does patient have CardioMEMS implant?	Yes=1 No=0	Chart audit
Confounding variable Comorbidities	Number of other chronic conditions the patient has been diagnosed with having.	One= 1 Two= 2 Three= 3 Four= 4 Multiple (> 5)= 5	Chart audit
Confounding variable Interventions	Intervention prescribed	None= 0 Weight check=1 Add diuretic= 2 Increase diuretic= 3 Decrease diuretic= 4 Stop diuretic= 5 IV diuretic in clinic= 6	Chart audit
Confounding variable Compliance	Was the patient compliant with the intervention?	Yes=1 No=0	Chart audit
Confounding variable Tobacco use	Patient current or previous tobacco use	Yes=1 No=0	Chart audit
Confounding variable Alcohol use	Patient current or previous alcohol use	Yes=1 No=0	Chart audit
Confounding variable Substance abuse	Patient current or previous abuse of prescription or illicit drugs	Yes=1 No=0	Chart audit
Clinical variable Admitting diagnosis	Patient main reason for/ diagnosis during hospitalization	Specific diagnosis that required admission to the hospital	Chart audit
Clinical variable Length of stay (LOS)	Amount of time patient was in the hospital.	0-2 midnights= 1 3-5 midnights= 2 6-8 midnights= 3	Chart audit

Clinical variable Acuity	The condition of the patient at admission to the hospital.	0= Undetermined: The patient's condition was unknown at this time. 1= Good: The patient's vital signs and overall condition was stable. 2= Fair: The patient's current condition was stable but there is a chance of deterioration. 3= Serious: The patient was very ill, and might have had unstable vital signs and overall condition is concerning. 4= Critical: The patient had unstable vitals and indicators for recovery were unfavorable.	Chart audit
Demographic			
Gender	Biologic determination	1. Male 2. Female	Chart audit.
Age Range	Chronological age in years	50-59= 1 60-69= 2 70-79= 3	Chart audit.
Race	Classification into groups based on ancestry or genetics	1. Black or African American 2. White	Chart audit
Marital Status		1. Married 2. Single	Chart audit

Table 2. Participant Demographics

Demographic	**Frequency** (N=14)	**Percent**
Age		
50-59	1	7.1
60-69	5	35.7
70-79	7	50.0
80-89	1	7.1
Gender		
Male	10	71.4
Female	4	28.6
Race		
African American	5	35.7
Caucasian	9	64.3
Marital Status		
Married	9	64.3
Single	5	35.7
Alcohol Use		
No	10	71.4
Rarely	1	7.1
Yes	3	21.4
Tobacco Use		
Former	8	57.1
None	6	42.9
Drug Use		
None	12	85.7
Cannabis	2	14.3

Table 3. Comparison of Patient Outcomes Pre and Post CardioMEMS implant

	Pre-CardioMEMS			Post-CardioMEMS			Paired t-test		
	Range	*M*	*SD*	*Range*	*M*	*SD*	*t*	*p*	*df*
Hospital Admissions	0-4	1.79	1.12	0-3	.64	1.51	2.655	.020	13
Emergency Room Visits	0-3	.79	1.05	0-3	.43	.85	1.099	.292	13
Unplanned Clinic Visits	2-16	7.29	5.53	0-15	6.29	5.35	.801	.438	13
Quality of Life (MLHFQ score)	31-88	52.91	16.60	3-40	18.36	11.57	6.480	.000	10

Table 4. Comorbidities

Comorbidities	**Number of patients effected**
Cancer	5
TIA	2
CVA	2
Anemia	1
Aortic insufficiency	1
CKD	2
Mitral valve regurgitation	1
Amyloidosis	1
Asthma	1
PAD	2
V- Tachycardia	1
HTN	6
Obesity	4
DMT ll	4
Cardiomyopathy	4
COPD	5
CAD	8
OSA	7
Interstitial lung disease	1
Hepatitis C	1
Pulmonary HTN	4
High cholesterol	5
Hyperthyroidism	1
Hypothyroidism	3
A-fib	5

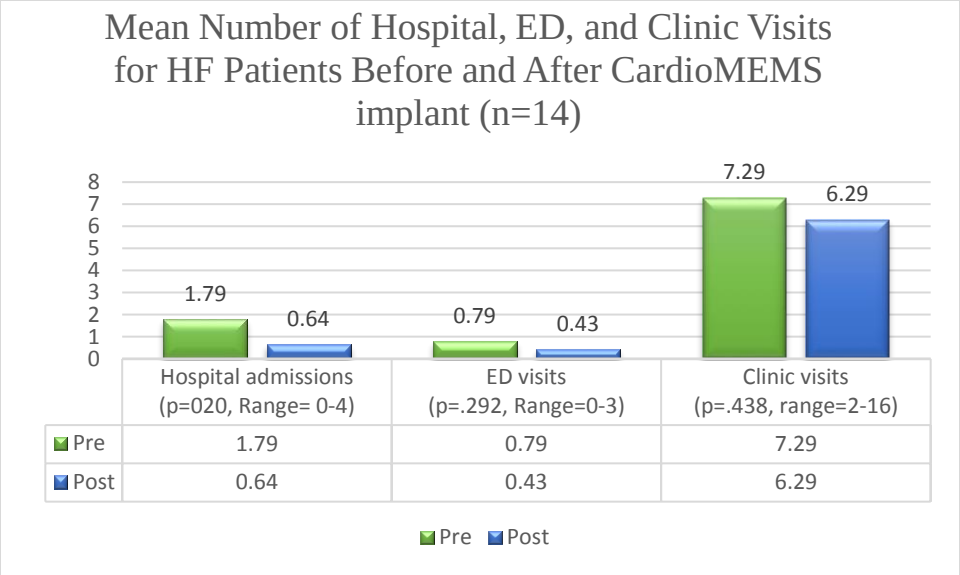

Figure 1. Patient outcomes pre and post-CardioMEMS implant

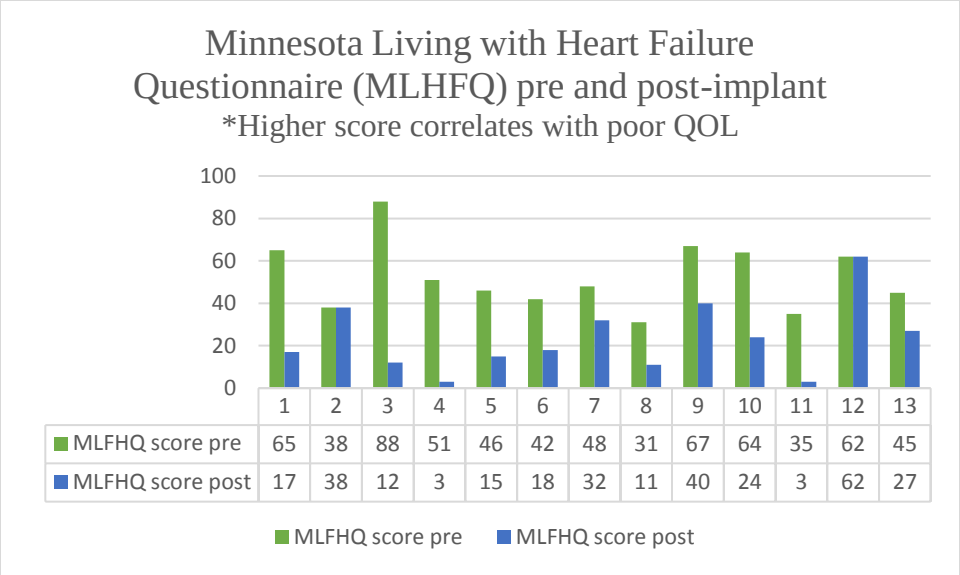

Figure 2. MLHFQ scores for each participant pre and post-CardioMEMS implant

Project Planner: Evaluation of CardioMEMS

Select a period to highlight at right. A legend describing the charting follows. Period Highlight 1 Plan Duratio Actual Start % Complete Actual (beyond plan) % Complete (beyond plan

ACTIVITY	PLAN START	PLAN DURATION	ACTUAL START	ACTUAL DURATION	PERCENT COMPLETE
Chose topic	1	5	1	4	100%
Creat PICOT	1	6	1	6	100%
Problem statement and background	4	4	4	5	100%
Significance and literature review	6	8	6	6	100%
Theoretical foundation and variables	10	2	10	8	100%
Method overview	12	3	12	6	100%
Intervention and data	14	4	14	5	100%
CITI training	18	2	18	5	100%
Procedure and timeline	22	2	22	6	100%
IRB application: Organization's IRB	26	40	26	120	100%
IRB application: GWU's IRB	50	21	50	26	100%

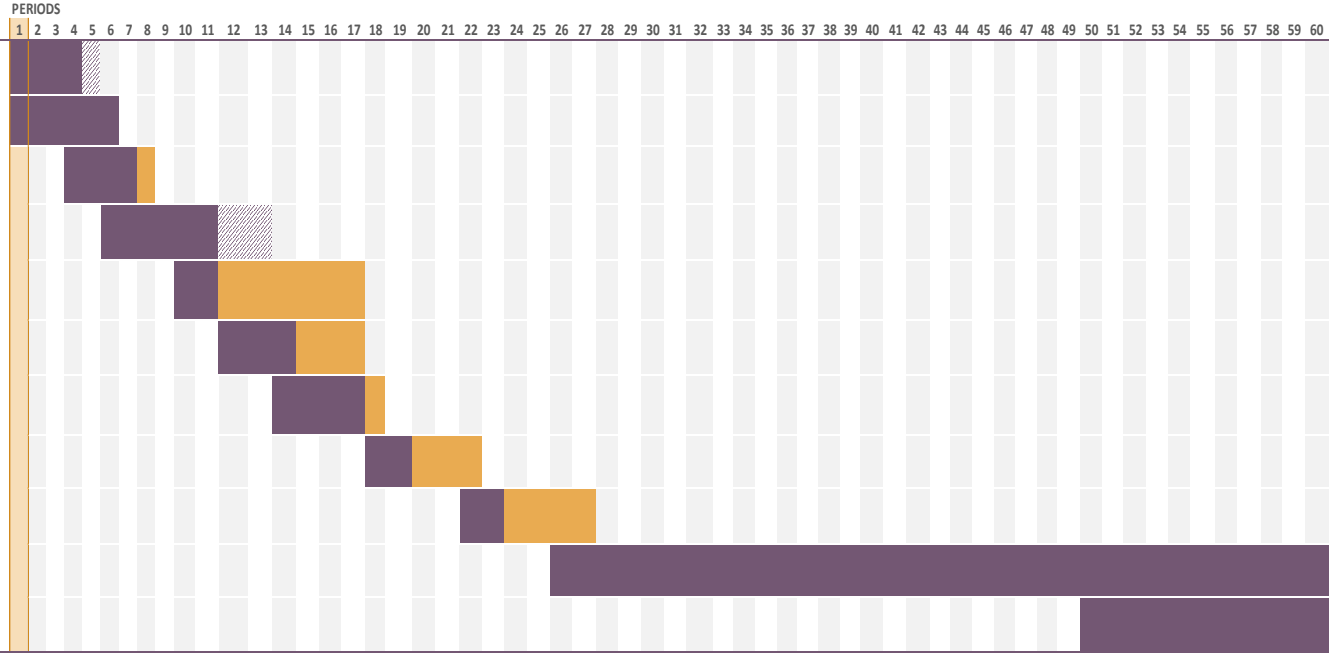

Chart 1. Gantt chart