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Patient-Centered Preimplant Education Session and Bi-weekly Text Message Adherence Reminders in Patients with a Newly Implanted CardioMEMs® Device: A Quality Improvement Study

Elizabeth M. Miller
University of Nebraska Medical Center

Alicia Abboud
University of Nebraska Medical Center

Audrey Cooper
University of Nebraska Medical Center

University of Nebraska Medical Center

College of Nursing

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By

Alicia Abboud BSN, RN, Audrey Cooper BSN, RN and Elizabeth Miller BSN, RN

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Jennifer Miller, PhD., APRN-NP, ACNPC-AG

Introduction

Heart failure is a pronounced disease in the United States, affecting over 6.2 million individuals and costing the nation an estimated 30.7 billion dollars (Virani et al., 2020). Costs are expected to rise with an aging population and reach approximately 70 billion dollars by 2030, with 80% of those costs related to hospitalization (Heidenreich et al., N.D. as cited in Adamson et al., 2016) Evidence-based guideline-directed medical therapy (GDMT) depends heavily on patient compliance, as well as awareness of associated symptoms of heart failure and active collaboration with the health care provider (Fonarow & Ziaeian, 2016).

National trends in heart failure diagnoses, hospitalizations, and re-admissions continue to increase at a costly rate (Agarwal et a., 2021). The concept of medical therapy compliance is an ever-present theme in any chronic disease management plan, with heart failure being at the center of this patient care challenge (Agarwal et a., 2021). To mitigate the adherence factor, research from the Altitude Survival Study (Saxon et al., 2010) showed a significant increase in one- and five-year survival rates in those with remote capable implantable defibrillators and cardiac resynchronization therapy devices compared to those with only clinic-follow-up for device and therapy monitoring.

The CardioMEMs® system was developed by Abbott© and is a small device placed in the patient's pulmonary artery via a minimally invasive procedure by an interventional cardiologist. The use of remote patient data from the CardioMEMs® device has been shown to reduce hospital re-admissions, facilitate tailored medication management, detect increased pulmonary artery pressures before clinical signs of decompensated heart failure, and improve patient quality of life (Givertz et al., 2017; Heywood et al., 2017; Costanzo et al., 2016 Haynes et al., 2020). The CardioMEMs® device enables the patient to send in daily pulmonary artery pressure readings to the provider via the remote capabilities of the device. In the first 2,000

patients' post-clinical trial in the United States, patient compliance with daily CardioMEMs® readings has been reported to be as high as 99% (Heywood et al., 2017), dropping to 85% in those one-year post-device implant (Shavelle et al., 2019). CardioMEMs® device adherence has been shown to improve patient and healthcare network outcomes; therefore, the focus of this project will be to improve patient compliance with daily remote CardioMEMs® readings using patient reminders beyond the standard of care within the Nebraska Medicine healthcare network.

Problem Statement

Heart failure is a rapidly growing problem in the United States, leading to decreased quality of life for individuals with the disease, caregiver burden, and increased healthcare costs to heart failure patients and healthcare systems. Remote pulmonary artery pressure monitoring with devices such as the CardioMEMs® device has been shown to improve outcomes in heart failure patients by improving quality of life, decreasing hospitalizations and hospital length of stay, decreasing hospital readmission rates, and lowering mortality (Adamson et al., 2016; Costanzo et al., 2021; Angermann et al., 2020; Givertz et al., 2017). By analyzing the pulmonary artery pressure daily, providers can titrate medications and suggest diet and fluid intake changes to prevent exacerbations from an outpatient setting.

Nebraska Medicine's outpatient heart failure program reports daily CardioMEMs® transmission compliance rates as low as 66-89% (Nelson, 2022) and has identified this as a quality improvement project needed to improve health care outcomes of patients and reduce hospitalizations. This quality improvement project incorporated a remote enhanced education session prior to implantation, allowing patients and their caregivers time for questions or concerns with the adherence guidelines. In addition to the standard of care, once weekly automated SMS reminders, patients received a secondary SMS text message reminder to utilize the pillow to transmit their data daily. To evaluate the outcomes of the project, a retrospective

review of patient records was conducted to compare the adherence rates pre and post intervention.

Purpose Statement

The purpose of this quality improvement project was to evaluate the effects of increased CardioMEMs® education and bi-weekly adherence reminders on data transmission rates, heart failure-related symptoms, physical and social functioning, self-efficacy, knowledge, quality of life, patient activation, and health care utilization. The PICOT was: In ambulatory heart failure patients with a CardioMEMs® device, how does a preimplant education session and bi-weekly text message adherence reminders affect daily compliance over a two-month time span? The aims of this study were to:

1. Collect the retrospective cohort for adherence data, via chart review, for the first eight weeks after CardioMEMs® implantation from January-December, 2022.

2. Design an enhanced, evidenced-based, pre-implantation educational program for patients with heart failure who plan on undergoing CardioMEMs® implantation.

3. Increase weekly standardized adherence text message reminders to two times weekly to enhance the use of remote CardioMEMs® monitoring and collect prospective adherence data for the first eight weeks after implantation.

4. Evaluate the demographic and clinical variables in relationship to patient activation, quality of life outcomes, and health care utilization in patients with heart failure with a newly implanted CardioMEMs® device. Baseline collection of patient activation, quality of life outcomes, and healthcare utilization will be compared to two-month post intervention collection of the same data points in the prospective cohort.

5. Perform comparison statistical analyses for retrospective cohort and prospective cohort CardioMEMs® adherence data comparing adherence rates from retrospective review of January 2022-December 2022 and two months following CardioMEMs® implant for the prospective cohort.

Review of Literature

In this literature review, 19 articles were reviewed to evaluate CardioMEMs® utilization, adherence, and the use of technology to improve adherence. All selected sources were determined to be peer reviewed and levels one through four qualities of evidence. Editorials, opinion pieces, pending clinical trials, and studies delayed to the COVID-19 pandemic were excluded from this review. Follow-up in the studies ranged from five days to two years. Studies specific to the CardioMEMs® device included participants with CardioMEMs® implantation criteria, at the time of the study, which includes Class III NYHA heart failure and at least one heart failure-related hospital admission in the past 12 months. Supporting evidence was found to show improvements in patient and healthcare system outcomes with the CardioMEMs® device and increased adherence of chronic condition management with technological interventions.

CardioMEMs® Improved Outcomes with Treatment Adherence

The CHAMPION trial (Givertz, 2017) was a single blind randomized clinical trial and was the first initial trial to evaluate the effectiveness of the CardioMEMs® device, The participants demonstrated 88% compliance to daily data transmissions alongside a 28% reduction in hospitalizations and 32% reduction in mortality rates among the treatment group. Research from Adamson et al., (2016) studied the same data as the CHAMPION trial but limited their study to Medicare patients finding a 49% decrease in hospitalization rates with the treatment group.

With an increased focus on adherence, European researchers studied heart failure management strategies and developed an algorithm for physician titration of heart failure medications based on pulmonary artery pressures (Angerman, 2020). The education component emphasized the importance of adherence to treatment and patients (n=234) demonstrated a median medication compliance of 87.6 %. This study focused on heart failure hospitalizations, pulmonary artery pressures, medication titrations, remote reading adherence, and health care provider compliance for weekly reading analysis. Results of the study showed a decrease of 62% in heart failure-related hospitalization rates compared to the year prior to implantation, a significant ($p<0.001$) reduction in pulmonary artery pressure from baseline, and a reduction in all-cause death rates. Similarly, Costanzo et al., (2016), used a comparable algorithm to titrate medications based on CardioMEMs® readings while the control group titrated medications based on clinical management and daily weights. The study found that twice as many medication titrations occurred in the active monitoring group compared to the blind monitoring group over a 6-month period (2,468 vs 1,061; $p<0.0001$). Diuretics were reported as the most titrated medication ($p<0.0001$) (Costanzo et al., 2020).

In addition to decreased hospitalizations and readmissions, utilization of the CardioMEMs® device reduced hospital length of stay from an average of 9.70 days for a heart failure admission pre- CardioMEMs® implantation to 3.70 days after implantation (Baginski et al., 2021). Mortality rates were reduced in many studies related to CardioMEMs® devices (Kotalczyk et al., 2022) as well as other remote heart failure implantable devices (Varma et al, 2015). An Altitude Survival Study, (Saxon et al., 2010), found a significant increase in one- and five- year survival rates with implantable remote capable devices such as defibrillators and cardiac resynchronization compared to only cardiac follow-up.

Adherence Data

Many of the studies in this review demonstrated high compliance in achieving improvements in hospitalizations, quality of life, and mortality (Haynes et al., 2020, Crnko et al., 2013). Haynes et al., (2020) aimed to understand the motivation for compliance and found that many patients self-report higher than documented adherence levels. The self-reported adherence rate was 89%, while the actual adherence provided by device data was 77.6% (Haynes et al., 2020). Studies have found that along with daily adherence, the timing of data transmission may play an important role in heart failure management (Crnko et al., 2013). In a study completed by Crnko et al., (2021), participants transmitted their pulmonary artery pressure readings six times per day for two days, then three times a day for three days, at the same time each day. Findings were that 70% of participants (n=10) had an increased pulmonary artery pressure from morning to night.

Technology Interventions

Several studies have used technology-based interventions, such as SMS text messaging, to enhance patient education sessions, increase adherence, and promote chronic disease management strategies. One study (Akdu-Zaheya and Shiyab, 2016) used a three-group randomized control trial that compared different doses of text messaging. The first group received three daily text messages on topics of medication compliance, diet management, and smoking cessation. The second group received one daily text message with generalized health information, and the control group received no text messages. The researchers found a significant difference ($p=.001$) in the experimental group versus the control and placebo group in terms of medication compliance. Furthermore, SMS interventions regarding diet recommendations showed a significant impact ($p<.05$) on the experimental and placebo groups versus the control group indicating that specific and generalized education regarding diet was impactful (Akdu-Zaheya and Shiyab, 2016).

Another study sent SMS text messaging to patient's post-discharge from coronary bypass surgery (Bikmoradi et al., 2022). Findings of this study showed there was a significant difference, ($p<0.001$), between the intervention arm receiving SMS reminders vs the control arm, in medication adherence and plan of care post coronary artery bypass graft surgery. Similarly, Assad (2018) used a phone-based survey to measure quality of life in patients with the CardioMEMs® device (Assaad, 2018). This study showed 57% improvement in dyspnea, increased activity tolerance, 70% of patients making diet changes, 43% had medication adjustments guided by their readings, changes in pulmonary artery pressure, and more awareness of their health status. These studies showed that patient awareness of pulmonary artery pressure may promote behavior change and self-management strategies.

Limitations of the CardioMEMs® Literature

There continues to be gaps in the pulmonary artery monitoring literature regarding adherence reminders with remote monitoring, quality of life metrics, and optimal education regarding the device. Previous research supports the use of remote patient monitoring in the cardiac patient to improve patient survival rates (Varma et al., 2015). Quality of life metrics currently reported as impacted by the CardioMEMs® system include the UTUAT, KCCQ, PHQ-9, and EQ-VAS, level III-IV evidence (Haynes et al., 2020; Angerman et al., 2020). Our quality improvement study incorporated a pre-implant education session with remote adherence reminders to improve care at a systems level. Furthermore, we studied whether the pre-implant education, session timing, remote delivery, and format of the adherence reminders improve adherence.

Conceptual and/or Theoretical Framework

This project's design was a Quality Improvement initiative, so the plan, do, study, act process was implemented as the conceptual framework for this project. The "plan" phase of the intervention involved an interdisciplinary collaboration with stakeholders at Nebraska Medicine Heart Failure clinic, including staff and nurses-with the support of the physician group. The "do" initiative for our project was initiated by promoting adherence of CardioMEMs® patients over a two-month period as well as implementing a pre-implant education session completed by the research team members. During the "study" phase of our project, we analyzed our adherence and outcome data. The final step in quality improvement was to "act" on our findings and results. The results were disseminated with the Nebraska Medicine Heart Failure clinic stakeholders and with the goal of publishing the study findings in a peer reviewed journal.

Design

Study Design

Quality improvement study with retrospective cohort chart review and prospective cohort intervention analysis.

Setting and sample

The setting of our study was the inpatient and outpatient Nebraska Medicine Heart Failure clinic/service line. Approximately 8-10 CardioMEMs® devices were implanted monthly. Enrollment for the study was continued for three months, in which we estimated we could enroll 6-8 per month for a total sample of 18-24 participants.

Tools/Measures-

Retrospective data on CardioMEMs® patients regarding compliance ratings were collected for the year 2022, January-December via the Merlin.com CardioMEMs® platform. One member of the research team members is employed at Nebraska Medicine as a transplant coordinator with the heart failure team giving her ethical access to the Merlin.com

website. Hospital re-admission data, for Nebraska Medicine, was reviewed and analyzed for all CardioMEMs® patients during the year 2022. Enrollment for the study began August 1, of 2023 and continued through October 31, 2023. We collected the first 8- weeks of CardioMEMs® adherence data on patients enrolled through October 31, 2023. Adherence data collection was completed by January 27, 2024.

Primary Outcome

The primary outcome measure was CardioMEMs® compliance with at least six out of seven days of the week, or 85% compliance. For optimal use of the CardioMEMs® device, daily transmissions are the recommendation from the CardioMEMs® company. This was measured via the Merlin website where daily readings can be observed and recorded by the research team.

Secondary Outcomes

Demographics- and Baseline Clinical Variables

The demographics to be collected include age, gender, race, insurance, and MRN. (See Appendix) Baseline clinical variables included New York Heart Failure class, use of beta blocker, ARNI or ACE/ARB, MRA, SGLT2, hydralazine, diuretic, and comorbidities. (See Appendix)

Measurements

Secondary outcome measures included the KCCQ, PAM, and Health care utilization. The Kansas City Cardiomyopathy Questionnaire (KCCQ) is a 23-item self-administered tool to measure patient-reported health status in patients with heart failure (Green et al., 2000). There are seven different domains measures including physical limitations (6 items), symptom stability (1 item), symptom frequency (4 items), symptom burden (3 items), self-efficacy (2 items), quality of life (3 items), and social limitations (4 items). These items were developed into cumulative scores for a total symptom score, a clinical summary score, and an

overall summary score (Hejjaji et al., 2021). The KCCQ-12 has shown test-rest reliability (Cronbach's alpha 0.66-0.95 (Green et al., 2000, Petterson et al., 2005, Hejjaji et al., 2021)

The original Patient Activation Measure (PAM) included 22 items and was developed and tested in the United States in 2004 (Hibbard et al. 2004, 2005). The PAM measures patient activation in four stages; 1) believing the patient role is in important, 2) having confidence and knowledge necessary to take action, 3) actually taking action to maintain and improve one's health, 4) staying the course even under stress. The original PAM 22 item Rasch person reliability was between 0.85 and 0.87 with Cronbach's Alpha at 0.87 (Hibbard et al., 2004).

Health care utilized was measured via the following: 1) Triage phone calls documented in EMR 2) One Chart Patient portal messaging threads 3) Medication changes as documented in EMR 4) Clinic Appointments 5) Inpatient hospitalizations 6) Provider initiated phone calls.

Table 1. Outcome Measures and Time of Measurement

Outcome Measures	
Measurement Title (primary/secondary outcome)	Time of Measurement
CardioMEMs® daily compliance (primary)	Daily
KCCQ- Kansas City Cardiomyopathy Questionnaire (secondary)	Baseline completed during remote education session, completed 2 months after SMS adherence reminder initiated
PAM- Patient Activation Measure (secondary)	Baseline completed during remote education session, completed 2 months after SMS adherence reminder initiated
Health Care Utilization (secondary)	During 2-month study period, EMR review

Participant Recruitment

Participants were recruited by the Nebraska Medicine Heart Failure services line. Education was provided to the Heart Failure and Transplant Team Nurses, who see patients in clinic on a varying schedule, via email throughout the two-month requirement timeframe. The education provided was focused on asking patients if they would be willing to receive a phone call about being in a research study for CardioMEMs® if they are eligible. Participants were identified by Heart Failure Nurse Coordinators, and Heart Failure and Transplant Coordinator and DNP students within the Nebraska Medicine Heart Failure team.

Scripting was provided by the research team for the recruitment process, available to clinic staff via email, and available on the clinic research notification bulletin board near the nursing computers at the heart failure staff location. The staff then notified the student team member for recruitment.

Nebraska Medicine Heart Failure Clinic: CardioMEMs® Standard of Care

Standard of Care Procedures.

Patients are seen in the Heart Failure clinic for medical management. If they have not previously been evaluated for a CardioMEMs® device and they have NYHA Heart Failure Class II or III, they are identified by the provider in clinic at their appointment or as an inpatient in the hospital. Patients are introduced to the CardioMEMs® device and given basic education per the provider in clinic or hospital which will be discussed in the next section.

Standard of Care Education.

Currently, the education provided to the patient is done independently by physician or APP in clinic or hospital, but quality and timing are variable and is provider dependent. If the patients are interested in immediate education, Merlin has an approximately 4-minute video booklet that they provide for the clinic to give patients to watch. Content covered in this video includes heart failure definition, class, diagnosis, signs & symptoms, and treatment options. It discusses what the CardioMEMs® device does, how it is implanted, how it works to read pulmonary artery (PA) pressures, risk related to procedure and how use can improve patient quality of life. The video also discusses that in a recent trial of 1200 patients with heart failure using CardioMEMs® decreased hospitalizations by 58% and if used correctly patients may have more medication and lifestyle changes prior to feeling symptoms (*Stay Ahead of Worsening Heart Failure | Abbott Cardiovascular*, n.d.). Once the patient has agreed to possible implantation, has been identified as a CardioMEMs® candidate the heart failure nurse case

managers are notified where they apply for insurance authorization. The patient, if agreeable to proceed are notified that they will be contacted by the Heart Failure Team if approved to get device and to be scheduled.

CardioMEMs®: Pre-Implantation.

Standard of Care Procedures Pre-Implementation

Once scheduled for CardioMEMs® placement, patients are given basic preoperative instructions for catheterization lab that include time to be NPO (nothing by mouth), when to arrive, where to check in, and what medications they need to hold. Patients are given instructions regarding the approximate length of time for procedure, post operative stay and that they will need a driver to take them home. No detailed education regarding the CardioMEMs® device is given.

CardioMEMs®: Post implantation Standard of Care

After implantation in the immediate post operative phase, the CardioMEMs® clinical representative reviews the education material. Patients are still on bed rest in this post operative period when receiving this education.

Education.

Post implant, the CardioMEMs® Nurse Representative via Merlin, meets with the patient and their caregiver for a more in-depth education session. Patients are in the post operative phase of receiving their implant and are provided with their CardioMEMs® "pillow" and instructions on how to use and troubleshoot. Merlin has a text message education system that patients can subscribe to that gives information about using their device and sending in readings. Patients are not required to subscribe to this text message education, but it is offered. The education focus of the CardioMEMs team is listed in the table below (see Table 2).

Table 2. CardioMEMs Education Focus and Description

Education Focus	Description
CardioMEMs Purpose and Function	The CardioMEMs® Heart failure system helps healthcare providers understand when patients heart failure is getting worse. This is described to the patient as the device measuring pressures in the lungs that rise when fluid increases because the heart is too weak for blood to pump effectively. Healthcare providers can then take steps to manage the heart failure symptoms or fluid levels before it has serious effects on the patients' quality of life or results in a hospitalization. Pulmonary artery pressure monitoring provides early detection of worsening heart failure, long before symptoms such as fatigue, shortness of breath, swelling of the feet, ankles and legs and weight gain. Daily pressure readings from home can proactively inform health care providers of any needed adjustments to your medications and/or lifestyle without a hospital or clinic visit.
CardioMEMs Daily Readings and Adherence	To encourage adherence, patients will be asked to make their daily readings part of their morning routine; if they forget and it is later in the day, best to resume the following day at the usual time. They do not have to 'set an alarm' just when they wake up.
CardioMEMs Transmission and Connectivity	They do not need a land line to transmit. It transmits via cellular (it will find a cell tower and ping off that to transmit). If they do live in a rural area with limited service, we can connect the pillow to their home WiFi. If they do not have WiFi, a land line will need to be used.
CardioMEMs Transmission pillow	Show them the pillow, it is larger than what most people think. Remind them that it takes 18 seconds to read. So, they are not on the pillow very long at all. They do not need to sleep on the pillow. Just pull it out every morning. It is recommended the pillow is plugged into a wall outlet, not a power strip. Frequencies from the other devices plugged into the power strip can cause an inaccurate reading.
CardioMEMs Team Communication	Patients likely will be called when they are feeling well and need to be reinforced that we are treating their heart failure before they may experience clinical symptoms.

Patient CardioMEMs® Home Procedures

After implantation and the patient is home, the patient is asked to apply the CardioMEMs® pillow 4-7 days per week for 18 seconds. The standard of care adherence at Nebraska Medicine for CardioMEMs® patients is 66-89%.

Standard Care Adherence Reminders as of April 2023

As of April 2023, the Nebraska Medicine Heart Failure team switched from sending automated phone call reminders on Mondays to sending automated SMS message reminders to patients to remind them to send in their CardioMEMs® readings. These SMS reminders are not individualized and sent on Monday mornings. There are a few patients who do not have the ability for SMS reminders and are still receiving the previous standard of care phone call reminders.

CardioMEMs® DNP Project Procedures

Retrospective Data Review

Retrospective data on CardioMEMs® patients regarding compliance ratings was collected for the first six weeks of implantation for the year January -December 2022, via the Merlin.com CardioMEMs® platform. One member of the research team is employed at Nebraska Medicine as a transplant coordinator with the heart failure team giving her ethical access to the Merlin.com website. Hospital re-admission data, for Nebraska Medicine, was reviewed and analyzed for all CardioMEMs® patients during the year 2022.

Participant Recruitment and Inclusion/Exclusion procedures.

Inclusion.

An inpatient or outpatient individual identified as a new implant CardioMEMs® candidate as defined by the CardioMEMs® FDA guidelines which include adults over the age of 19, NYHA Heart Failure Class II or III, at least one heart failure hospitalization in the last 12 months and/or an elevated brain natriuretic peptide. Patients who have the technology to participate in the CardioMEMs® remote monitoring system (landline telephone system, mobile calling devices as a primary means of communication, wireless internet).

Exclusion.

Any patient undergoing CardioMEMs® implant without FDA indications. Patients FDA contradiction to receiving a CardioMEMs® device. Pregnant patients due to the fact that none have been implanted at Nebraska Medicine prior to this study and inability to participate GDMT due to harm to the fetus. Any patients on hospice and or receiving end of life care as indicated by ICD codes in the EMR. Any patient unable to participate in the standard technical requirements for remote monitoring of the CardioMEMs® device such as a patient who was seen in clinic for device interrogation without remote monitoring capabilities due to no landline or mobile phone technology.

Pre-implantation procedures.

Education.

The enhanced education for this research project was an individualized zoom education session with a member of the DNP research team approximately one week prior to CardioMEMs® implant. The education provided to patients and their caregivers by the DNP team was the same education that is currently provided via Merlin CardioMEMs® nurse representative post implant (see CardioMEMs® Post Implantation, Education). Pre-established education handouts per Merlin for CardioMEMs® education was provided to patients. Education of CardioMEMs® device and use was reviewed as well as education regarding the importance of sending in readings, how this will affect their quality of life, potential for frequent medication adjustments and potential for keeping patient out of the hospital. The DNP Research team participated in live education with the CardioMEMs® representative to make sure they are reviewing the same education pre implant that is reviewed post implant.

Post implantation procedures.

Education.

The standard of care post implant education via the Merlin CardioMEMs® nurse representative remained the same done immediately post operatively with patient and caregiver. Patients were still offered the text message education route via Merlin and could enroll independently by choice.

CardioMEMs® study: Adherence Reminders.

An additional adherence reminder sent via SMS messaging via the Merlin.net website was implemented in addition to the standard of care SMS reminders. These reminder SMS messages were not individualized but a pre-determined text reminding patients to send in their CardioMEMs® readings. SMS reminders were sent every week on Thursday to offset the standard of care weekly SMS reminder done on Mondays for the first 8-weeks after

implantation. Patients enrolled in the study consented to accepting these text message reminders sent through the Merlin.net system.

Sample Size Estimation

Completed with G*Power 3.1 (Faul, Erdfelder, Lang, & Buchner, 2007). Using the Wilcoxon Mann-Whitney test with Alpha α=0.05, Power= 0.80 and using a medium effect size= 0.50, it was determined that we needed 134 participants enrolled in the study for there to be significant power. As this is a quality improvement study, it was underpowered for statistical hypothesis testing, and analyses focused on descriptive statistics and hypothesis generation informed by the aims.

Analysis

Missing data was evaluated but was not substituted. Each statistical test was conducted at p=.05 level. The KCCQ and PAM were scored per the published scoring manuals. Descriptive statistics, in particular counts and percentages, was used to measure patient adherence in Aims 1 and 3. Aim 4 was assessed with descriptive statistics and correlational methods to explore the relationships between adherence, patient activation, quality of life outcomes, and healthcare utilization. In Aim 5, the comparison of adherence between the retrospective and prospective cohorts was conducted with a Wilcoxon Mann-Whitney test. Additional relationships between demographic and outcomes variables was assessed with Wilcoxon Mann-Whitney and correlational methods as appropriate.

Significance and Sustainability

Patients with CardioMEMs® devices have been shown to an improvement in the management of their illness as well as a significant decrease in hospitalizations related to their heart failure diagnosis. Research on the interventions to increase CardioMEMs® compliance is limited. This project will be impactful to our stakeholders as this technology is already in use at

Nebraska Medicine and available on the Merlin platform. This quality improvement study will assist in studying patient adherence and seek to improve outcomes for patients with heart failure and the related health care system.

Results

Participants were recruited August-November 2023. The project was extended by two months with the permission of Nebraska Medicine Heart Failure service and PGNA to facilitate participant recruitment during a time of low implants numbers. There were 10 total participants recruited to participate in the study. One participant was withdrawn during the study period due to hospice placement. Age and race demographics: mean age was 67.7 (48-85), males (8), females (2), Caucasian (9), Black/African American (1). Insurance providers: Medicare (9), Medicaid (2), and private (1). NYHA prior to intervention: NYHA class II (3), NYHA class III (7). NYHA post intervention: NYHA class II (3), NYHA class III (6), NYHA class IV (1).

Goal directed medical therapy (GDMT) as relates to heart failure and symptoms management pharmaceuticals were measured for all participants pre- and post- intervention. Beta blocker therapy pre-intervention (7), post intervention (8). Angiotensin receptor antagonist (ACE), angiotensin receptor blocker (ARB), or angiotensin receptor/neprilysin inhibitor (ARNI) pre intervention (8), post intervention (7). Mineralcorticoid receptor antagonists (MRA) pre intervention (6) post intervention (9). Sodium-glucose cotransporter-2 (SGLT2) pre intervention (8), post intervention (7). Hydralazine pre-intervention (1), post intervention (2). Diuretic therapy pre-intervention (9), post intervention (10). Diuretic titration, increased or decreased, occurred for more than half of the study participants (n=7). During the study period, 60% of participants (n=6) had an increase in their diuretic dosing while 10% (n=1) had a diuretic dose reduction.

Retrospective cohort data from January-December 2022 was collected and reviewed. The adherence rate for this period was 74.8%. The intervention group had an adherence rate of 85%. A Mann-Whitney *U* test was performed indicating no significance between the intervention group and retrospective group compliance/adherence data for daily remote CardioMEMs® reading transmission (U=74.0 p= .381).

Of the ten participants that were implanted with a CardioMEMs® device in our study, all ten received the remote education session prior to implantation. All ten participants received biweekly SMS reminders, increased from the standard of care with once weekly SMS reminders.

The PAM and KCCQ surveys were administered via phone pre-intervention and post-intervention 8 weeks following CardioMEMs® implantation. (n=9). The PAM survey measured patient activation while the KCCQ measured quality of life as related to heart failure. Pre intervention PAM scores ranged from 39-52 (μ= 43.20 SD$\pm$ 5.029). Post intervention PAM scores ranged from 35-52 (μ=42.44, SD$\pm$5.918). A related-samples Wilcoxon signed rank test was performed finding no significance between pre and post intervention PAM scores (p=0.672, significance level 0.05.). Pre intervention KCCQ scores ranged from 27-62 (μ= 41.30, SD$\pm$ 11.851). Post intervention KCCQ scores ranged from 28-63 (μ= 48.78, SD$\pm$ 12.316). A related-samples Wilcoxon signed rank test was performed finding no significance between pre and post intervention KCCQ scores (p=0.672, significance level 0.05). There was a significant positive Pearson's correlation noted in comparing the post intervention PAM and post intervention KCCQ scores at 0.707 (p=0.33, significance level 0.50).

Healthcare utilization was measured in terms of outpatient clinic visits, emergency room visits, and hospital admissions. In participants with higher compliance (median=100%), hospital

admissions were lower compared with those with lower compliance (median=67%). This is a statistically significant difference with the Mann-Whitney U test (U=1.5, p=0.020).

Discussion

The primary purpose of this quality improvement project was to determine if a preimplant education session and an increase in weekly SMS reminders to bi-weekly reminders would increase participant compliance in daily remote CardioMEMs® transmissions to 85%. A comparison of retrospective data was performed with the intervention group adherence data. Retrospective adherence data was collected from January-December 2022 with the assistance of the Nebraska Medicine Heart Failure service. One member of the DNP group is a nurse coordinator with the Nebraska Medicine Heart failure team providing ethical access. The mean retrospective data adherence was measured at 74.8% indicating those with a CardioMEMs® device were adherent with sending in daily remote readings 74.8% of the time in January - December 2022. Our results did not show a statistical significance (p = .381) between the DNP project group (median compliance= 85.0) and the retrospective comparison group compiled from CardioMEMs® compliance at Nebraska Medicine in 2022 (median 74.0). While the results were not statistically significant, there is implication for clinical significance as the goal of the quality improvement project was to increase compliance to 85%, which was achieved, and is consistent with compliance ratings reported in previous literature (Shavelle et al., 2019).

This quality improvement showed that preimplant education sessions were feasible and enhanced adherence. All participants completed the remote education sessions. Sessions were completed remotely and took under 30 minutes. The preimplant education sessions can be clinically correlated with the improved daily remote adherence rates of 85%. Streamlining this process for staff RNs, especially as a remote option for staff and patient convenience, has the potential to increase daily remote adherence. Patient education interventions have been shown to

be an effective way to manage costs in the healthcare system in an overwhelming abundance of advancing technology (Stenberg et al., 2018).

All study participants received an additional SMS reminder, along with the once weekly standard of care SMS reminder, to send in daily remote CardioMEMs® readings. The use of SMS reminders for outpatient management of medical treatments has shown significant impact on therapies such as medication compliance, diet management, and smoking cessation (Akdu-Zaheya and Shiyab, 2016). The use of bi-weekly SMS reminders for the intervention group did clinically correlate with an increased daily remote adherence measured at 85%. Furthermore, increasing the SMS reminder to bi-weekly for CardioMEMs® patients was no additional cost to the healthcare organization versus the standard of care once weekly SMS reminder.

Our project studied heart failure-related symptoms, physical and social functioning, self-efficacy, knowledge, quality of life and patient activation, measured with the PAM and KCCQ surveys pre and post intervention. There was no statistical significance between pre and post PAM and KCCQ scores, however, there was a positive correlation (Pearsons Correlation 0.033, P=0.05) between post PAM and KCCQ scores. Previous quality of life measures reported in the literature as relates to the CardioMEMs® device includes The Unified Theory and Use of Technology (UTUAT), KCCQ, Patient Health Questionnaire (PHQ-9), and EurQol Visual Analog Scale (EQ-VAS). Surveys administered in the literature were performed at various times after implant up to two years following implant. There was no research found utilizing the PAM which this study provides (Haynes et al., 2020; Angerman et al., 2020). Our project builds upon the current patient activation science in heart failure patient populations.

Furthermore, previous literature has supported the outpatient titration of medications, specifically diuretics, as clinical usefulness of the CardioMEMs® device (Costanzo et al., 2021).

In our study group, over half (60%) of participants experienced an increase in their diuretic therapy supporting the use of the CardioMEMs® device to optimize outpatient management of heart failure improving the quality of life for patients and ultimately reducing 30-day hospital re-admission in those with heart failure, impacting the financial success of the healthcare organization.

Our study measured healthcare utilization, analyzed in three categories: outpatient clinic visits, emergency room visits, and 30-day hospital re-admissions. Previous research from the CardioMEMs® device has supported decreased re-admission rates, up to 30%, for those who have a CardioMEMs® device (Givertz, 2017). Amongst the study participants, our results did show a statistical significance in the decrease of 30-day hospital re-admission rates/HCU3 (U= 1.5, p = 0.020) between those with higher compliance rates (median = 100%) compared to those with lower compliance (median= 67%).

Limitations

The limitations of this research include the small sample size, consolidation of healthcare utilization, inability to verify patient acknowledgment of the SMS intervention, and the short follow up for assessing patient adherence. As discussed in the study design, trends for CardioMEMs® implantation at Nebraska Medicine were 6-8 patients per month with the potential to enroll 18-24 participants however our enrollment was only 10 participants. A G*Power 3.1 (Faul, Erdfelder, Lang & Buchner, 2007) analysis was completed and to achieve a Power=0.80 and Alpha =0.05 the study would have required 134 participants. Based on chart reviews at the completion of our study healthcare utilization was condensed into outpatient, emergency room, and hospital admission occurrences versus the five encounters in our proposal. There was no way to confirm our study participants acknowledged their SMS reminders.

Following the participants for a longer duration than two months would have given more insight into long term utilization of the CardioMEMs® device or following the patients after an inpatient stay would have provided more insight to the financial implications of the device.

Conclusion

A preimplant education session and increase in weekly SMS reminders to biweekly did improve daily remote CardioMEMs® reading transmission in our study group to the pre-study established goal of 85% compliance. The remote education session has the potential to be streamlined to independent learning for CardioMEMs® patients or completed remotely for the convenience of the patient and the educating nurse, as all sessions in this study were done remotely. The bi-weekly SMS reminders were at no additional cost to the organization via the CaridoMEMs® platform Merlin, and an economic resource to help increase compliance levels with daily remote monitoring transmission. Further research is applicable in what motivates the patient to comply with daily tasks related to his/her healthcare and further assessment of Heart failure-related symptoms, physical and social functioning, self-efficacy, knowledge, quality of life and patient activation in the patient with a CardioMEMs® device.

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Appendix

Variable Name	Source	Code (if applicable)	Level of Measurement	Measurement Points
Age	**Medical Record**	**NA**	**Interval**	**Beginning of study**
Gender	**Medical Record**	**0= Male** **1= Female**	**Nominal**	**Beginning of study**

Race	**Medical Record**	**0= White 1= Black 2= Hispanic 3= Asian 4= Other**	**Nominal**	**Beginning of study**
Insurance	**Medical Record**	**0= No Insurance 1= Medicare 2= Medicaid 3= Private Insurance**	**Nominal**	**Beginning of study**
MRN	**Medical Record**	**NA**	**Interval**	**Beginning of study**

Appendix

Variable Name	Source	Code (if applicable)	Level of Measurement	Measurement Points
NYHA heart failure class	**Medical Record**	**1= NYHA Class II 2= NYHA Class III**	**Ordinal**	**Beginning and End of Study**
Beta Blocker	**Medical Record**	**0= Yes 1= No**	**Nominal**	**Beginning and end of study**
ARNI or ACE/ARB	**Medical Record**	**0= Yes 1=No**	**Nominal**	**Beginning and end of study**

MRA- Mineral Corticoid Receptor Antagonist	**Medical Record**	**0=Yes 1= No**	**Nominal**	**Beginning and end of study**
SGLT2- Sodium Glucose Cotransport 2 Inhibitors	**Medical Record**	**0=Yes 1=No**	**Nominal**	**Beginning and end of study**
Hydralazine	**Medical Record**	**0= No 1=Yes**	**Nominal**	**Beginning and end of study**
Diuretic	**Medical Record**	**0= No 1= Yes 2= Titration up 3= Titration down**	**Nominal**	**Beginning and end of study, weekly during study**
Comorbidities	**Medical Records**	**0= Hypertension 1= Coronary Artery Disease (CAD) 2= Valvular Heart Disease 3= Hyperlipidemia 4= Obesity 5= Diabetes Mellitus 6= Obstructive Sleep Apnea 7= Pulmonary Hypertension 8= Gastroesophageal Reflux Disease (GERD) 9= Tobacco Abuse Disorder 10= Alcohol use disorder 11= Depression 12= Chronic Kidney Disease (CKD) 13= ICD or pacemaker implantation**	**Nominal**	**Beginning and end of study**