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Comparison of Traditional Management of Heart Failure with CardioMEMS

Quinn Jacobs
University of North Dakota

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Quinn Jacobs, RN-CEN, PA-S
Contributing Author: Julie Solberg, MPAS, PA-C
Department of Physician Assistant Studies, University of North Dakota School of Medicine & Health Sciences
Grand Forks, ND 58202-9037

UND SCHOOL OF MEDICINE & HEALTH SCIENCES
UNIVERSITY OF NORTH DAKOTA

Abstract

The purpose of this research and literature review is to compare the efficacy of the implantable pulmonary artery pressure monitoring device, CardioMEMS, to traditional heart failure management in terms of reducing hospital readmissions. The data bases of Cochrane Library, PubMed, Clinical Key, and DynaMed Plus were utilized. Because the CardioMEMS device is relatively novel in the treatment of heart failure, the time frame of search results was expanded to 10 years to include research from the original clinical trials. A total of 17 peer reviewed works were chosen for this review which included meta-analyses, systematic reviews, randomized controlled trials, and longitudinal studies. Current literature indicates that the CardioMEMS device promotes earlier detection of worsening congestive heart failure than traditional management methods. Earlier detection of increasing pulmonary artery pressures allows for earlier corrective interventions, making CardioMEMS more effective in reducing heart failure related readmissions. The data also indicates that the device is cost-effective as well. However, CardioMEMS may not be appropriate or cost effective for patients with end stage heart failure or limited life expectancy. Additional studies are currently underway to examine the efficacy of the CardioMEMS device in a broader range of patients as it is currently only FDA approved for New York Heart Association class III heart failure patients.

Introduction

- Approximately 6.5 million Americans have heart failure and in 2017 it contributed to one out of eight deaths. (CDC, 2020).
- It is estimated that heart failure has an annual cost of over $30 billion in the United States (CDC, 2020).
- Heart disease is the leading cause of death overall, not only in the US, but worldwide.
- Heart failure was the leading cause for hospital readmissions among Medicare patients in the year 2011 with a total of 134,500 readmissions within 30 days. This number far exceeds readmissions from any other condition (Agency for Healthcare Research and Quality, 2014).
- In 2014, the US FDA approved the first of its kind implantable pulmonary artery pressure monitor, the CardioMEMS. The device is surgically implanted in a pulmonary artery during a right heart catherization procedure. The device is then able to continuously monitor several data points including heart rate, systolic, diastolic, and mean pressures which are transmitted and collected daily with a pillow-like monitor that the patient lays on. The data is then transmitted via cellular signal, land line, or Wi-Fi to an online portal whereby the patient's provider is able to review the data and detect changes in pulmonary pressures that would warrant intervention.

Statement of the Problem

- Heart failure patients have historically been managed and monitored using a variety of methods including at home patient monitoring of blood pressure and weight in conjunction with frequent clinic visits, lab work, and medication therapy. Newer methods include nurse-led heart failure management programs which involve frequent clinic visits, medication titration, and follow up phone calls.
- One issue with traditional management of heart failure is that it requires patient compliance with treatment plans and recognition of the development of physical signs and symptoms that may indicate acute exacerbations. Data now shows that by the time the patient develops recognizable physical symptoms, pulmonary congestion and associated complications have already reached levels potentially requiring hospital admission (Adamson, 2009).

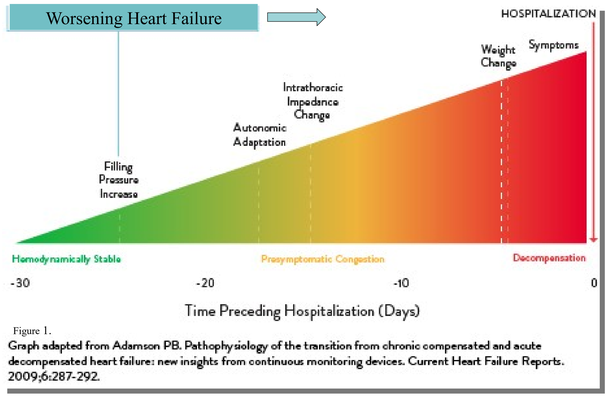

Figure 1.
Graph adapted from Adamson PB. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. Current Heart Failure Reports. 2009;6:287-292.

Research Question

- In patients with heart failure, do interventions based on monitoring pulmonary artery pressures with an implantable CardioMEMS device versus traditional methods lead to decreased hospital readmissions?

Literature Review

Efficacy of Traditional Medical Management in Heart Failure

- Neither weight gain of ≥ 5 pounds in one week nor increase in peripheral edema were reliable predictors for heart failure related hospital admission. However, an increase in dyspnea over both 7 and 14 days correlated with a greater number of hospital admissions (Howie-Esquivel et al. 2019).
- Elevation from baseline of natriuretic peptide levels is directly associated with risk of either a heart failure related hospitalization, cardiac death, or aborted cardiac arrest across all patient subgroups (Myhre et al. 2018).
- For patients enrolled in an integrated case management group, the 30-day readmission rate was 18.4% in comparison to the traditional treatment group in which the 30-day readmission rate was 52.6% (McCants et al. 2019).
- Heart failure patients managed by nurse-led medication titration had a 21% reduction in all cause hospital readmissions, 39% reduction in heart failure-related hospital admissions, and 34% reduction in overall mortality compared to traditional management alone (Driscoll et al. 2015).

Efficacy of CardioMEMS in Management of Heart Failure

-When examining data from the original **CHAMPION trial**:

- In the CardioMEMS treatment group there was a decrease in baseline of pulmonary artery pressures, a decrease in hospitalizations of up to 37%, a reduction in overall hospital days, and in improvement of quality of life (Gronda et al. 2020).
- In the CardioMEMS monitored treatment group, the patients with the highest baseline pulmonary artery pressures (>35mmHg) had the biggest impact with an initial mean baseline pressure of 43.4 $\pm$ 5.7 that was reduced to 37.8 $\pm$ 7.8 mmHg (Heywood et al. 2017).
- CardioMEMS demonstrated a 30% reduction in heart failure related hospitalizations when compared to traditional standard of care monitoring as well as a 45% reduction of all-cause hospitalizations at 6 months and 16% at 18 months (Veenis et al. 2020).
- An exponential relationship between the number of days between data transmission from the CardioMEMS device and number of days spent hospitalized as a result of heart failure was noted as well as between mean number of days between CardioMEMS data interpretation by health care professionals and heart failure hospitalization days (Tran et al. 2019).

- In the European **MEMS-HF trial**:

- Heart failure related hospitalizations were reduced by 62% in the CardioMEMS treatment group. Survival rate at 1-year post CardioMEMS implantation was 86.2%. Freedom from device related complications at 1-year was 98.3% (Angermann et al. 2020)

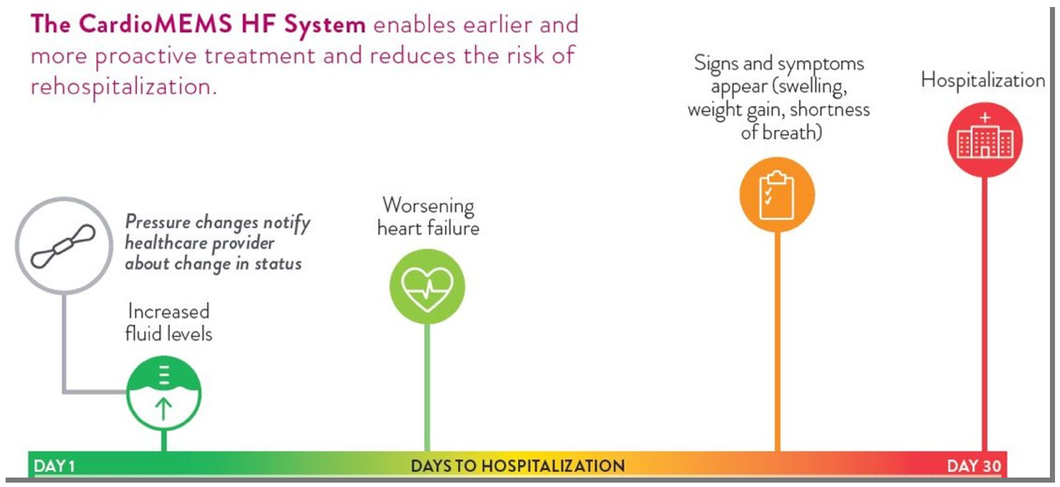

Figure 2. Retrieved from https://www.cardiovascular.abbott/us/en/patients/living-with-your-device/heart-failure/pulmonary-pressure-artery-monitoring/cardiomems-hf-system/ht-tab/set-up.html

Discussion

Traditional Management of Heart Failure:

- Home monitoring of weight gain alone is not likely adequate in terms of prevention of heart failure related hospitalizations. This is attributed to the finding that by the time an increase in weight and peripheral edema is noticed, the patient has already developed significant pulmonary congestion that may need more intense treatment than what can be provided on an outpatient basis (Howie-Esquivel et al. 2019).
- Management based on symptom development and physical changes alone depends in large part on the ability of the patient to recognize these symptoms. Patient ability to comply and recognize warning signs should be assessed on an individual basis.
- The reliability of assessing for elevations in natriuretic peptide levels for the prevention hospitalizations would obviously depend directly on the frequency and timing of lab monitoring. Waiting until the patient is symptomatic with dyspnea and peripheral edema would not likely be effective in preventing hospital readmissions.
- For heart failure patients who are not candidates or who decline more invasive methods of monitoring, the most efficacious method of management when looking at the goal of preventing hospital readmissions is integrative case management; This would involve a combination of patient symptom monitoring, frequent follow up phone calls, natriuretic peptide monitoring and associated medication adjustments. This method would allow for a custom-tailored treatment plan based on individual patient needs allowing for interventions in a timely manner through a team-based approach.

CardioMEMS for the Management of Heart Failure:

- Reduction in heart failure readmissions through pulmonary artery pressure monitoring would presumably increase quality of life by limiting symptoms of acute pulmonary congestion, dyspnea, and activity intolerance.
- The availability of data from the CardioMEMS device allows providers to intervene and make adjustments to heart failure medications early on in the development of pulmonary congestion in order to prevent acute exacerbations and subsequent hospitalizations
- There was a significant correlation between reduction of hospitalized days and the frequency of patient data transmissions from the CardioMEMS device as well as frequency of provider interpretation of the data (Tran et al. 2019). These results serve as an important reminder of the need for evaluation, interpretation, and potential intervention in terms of the overall effectiveness of technologic advances. As CardioMEMS becomes more popular, it may be helpful to incorporate these patients into a heart failure case management clinic for best results. This would ensure timely interpretation of results as well as proper intervention based on pre-determined guidelines.
- According to Abbott Laboratories, the sole contraindication for CardioMEMS therapy is inability of the patient to take dual antiplatelet or anticoagulant therapy for one month post implantation. Patients who do not meet these criteria may encounter difficulty attaining insurance coverage for the procedure.
- There are currently trials underway that will attempt to prove the efficacy of the CardioMEMS device for a broader range of heart failure patients as it is only FDA approved for New York Heart Association class III heart failure patients. Approval of the device for the management of patients with less severe heart failure could potentially minimize the progression of heart damage and improve life expectancy if monitored appropriately.

Applicability to Clinical Practice

- As heart disease continues to be the leading cause of mortality world-wide, it is without question that it is important for health care providers to remain educated on advances in treatment as well as changes in best practices for care.
- Customized treatment regimens tailored to the heart failure patient's individual needs will not only improve quality of life but potentially reduce cost to the patient as well as the payer.
- The implantable CardioMEMS device is an effective and perhaps under-utilized method of management for the heart failure patient. Through early detection of increasing pulmonary artery pressure, providers are able to make adjustments in medication therapy and potentially prevent need for hospitalization.
- By preventing acute heart failure exacerbations, the progression of damage to the heart and decline in cardiac function can be minimized.

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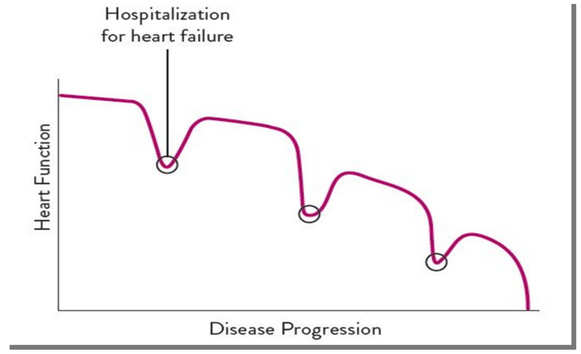

Figure 3. Retrieved from https://www.cardiovascular.abbott/us/en/patients/living-with-your-device/heart-failure/pulmonary-pressure-artery-monitoring/cardiomems-hf-system/ht-tab/set-up.html