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CardioMEMS in Heart Failure Management: Failure is Not the Only Option

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CardioMEMS in Heart Failure Management: Failure is Not the Only Option

Nursing 997: Independent Study

University of North Dakota College of Nursing and Professional Disciplines

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CARDIOMEMS IN HEART FAILURE MANAGEMENT

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PERMISSION

Title CardioMEMS in Heart Failure Management: Failure is Not the Only Option

Department Nursing

Degree Master of Science

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Abstract

Heart failure is a very complex disease process that causes significant morbidity and mortality, along with substantial costs to our health care system due to frequent emergency room (ER) visits and hospital admissions. Heart failure is often monitored and managed by clinical assessment alone. However, the classic signs of volume overload present when the patient's condition has deteriorated significantly, often requiring hospital admission. The subject of this case report is a forty-five-year-old female with a significant medical history of hypertension, diabetes mellitus, and hypercholesteremia that were poorly controlled. A lack of control over these disease processes can ultimately lead to the development of heart failure. Heart failure is a common reason for emergency room (ER) visits and hospital admissions, thus driving up the cost of our health care system significantly. The aim of this case report was to research and examine if pulmonary artery (PA) pressure monitoring devices such as the CardioMEMS device can help decrease unnecessary emergency room visits as well as hospital admissions.

An inclusive search strategy was conducted utilizing the University of North Dakota (UND) Harley E. French Library of the Health Sciences website all available literature pertinent to this topic. The literature review was conducted using both CINAHL and PubMed databases. The term "CardioMEMS" was searched in CINAHL with publication dates in the last five years that were published in English language and were peer reviewed. This search resulted in a total of twenty-two articles. The term "CardioMEMS" was also searched in PubMed for all literature that was published within the past five years, written in English, and was peer reviewed. There was a total of seventeen matches, which was then filtered through for articles only discussing ER visits and hospital admissions. A total of fifteen articles from both CINAHL and PubMed that provided the highest level of evidence were utilized to examine if pulmonary artery pressure

monitoring with a device like CardioMEMS can help reduce ER visits and hospital admissions in patients with heart failure.

Background

Uncontrolled blood pressure is a major risk for the development of heart failure. When pressure in the blood vessels is too high, the heart is forced to work harder to circulate blood throughout the body. Over time, this process causes the muscles in the heart to enlarge and become weak, eventually causing heart failure. Uncontrolled diabetes mellitus and atherosclerosis can also contribute to the development of heart failure due to the elevation of lipid levels (American Heart Association, 2017). This case report discusses a patient who presented with uncontrolled hypertension and diabetes, which may eventually lead to the development of heart failure. We will review the evidence regarding pulmonary artery pressure monitors such as CardioMEMS and how they impact the management of heart failure patients, specifically the potential to decrease hospital admissions and ER visits.

Heart failure is a complex disease process that affects more than six million Americans and contributes to approximately one million hospitalizations per year, making it the most common reason Americans are admitted to the hospital than any other condition (Ollendorf, Sandhu, Pearson, 2016). This disease creates a significant cost to the national healthcare expenses. The health care cost in the United States related to heart failure management is projected to increase from thirty-one billion dollars per year in 2012 to seventy billion in 2030 (Abraham et al., 2016). Furthermore, despite the advances in medical care and the pharmacological advances made in recent years, heart failure remains a significant contributor to increased morbidity and mortality.

Despite healthcare provider's and patient's best efforts, traditional tools to monitor fluid volume including daily weights and self-assessment are limited.

The technological advances of remote pulmonary artery pressure monitoring allows clinicians to take on a more proactive and preventative method in monitoring patients with heart failure. Changes in pulmonary pressures can occur up to two weeks prior to clinical signs and symptoms appear (Zile et al., 2008). The CardioMEMS device can remotely alert the provider if PA pressures are increasing, thus allowing for medication adjustments and interventions prior to acute decompensation. The purpose of this report is to review the literature with the highest level of evidence in order to determine if CardioMEMS can help decrease frequent and often unnecessary ER visits and hospital admissions.

Case Report

A forty-five-year-old Caucasian female with a significant history of hypertension, diabetes mellitus, and hypercholesteremia presented to the clinic with complaints of fatigue and a twenty-pound weight gain in the last three months. She relates her fatigue to the fact that she is waking up approximately every three hours to urinate, which is new within the last month. Her fatigue throughout the day makes her feel like she is unable to concentrate while at work and reports taking an hour long nap every day in the afternoon, which she never did previously. Physical exam reveals +1 pitting edema to bilateral lower extremities. Extremities were cool to touch, +2 lower extremity pulses present. Breathing is non-labored and clear to auscultation. Positive hepatic jugular reflex. S3 heart sound present. Her blood pressure was 158/98, pulse of 80, respiratory rate of 80, and temperature of 98.6 degrees.

Her current medication regimen includes Metformin 500 mg once daily, aspirin 81 mg, Lisinopril 20 milligrams, atorvastatin 20 milligrams, and a multivitamin daily. She has not been

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taking her prescribed Metformin due to gastrointestinal upset. Her blood sugars have been running between 175-250 in the morning. She does not take her post-prandial blood sugars and did not bring in her blood sugar log with her. Her blood pressure on exam was 158/98. She does not have a blood pressure machine at home and stated she only gets her blood pressure checked when she goes to the doctor. She admitted that she often forgets to take her other medications including her aspirin, Lisinopril, and atorvastatin.

The basic metabolic panel showed a glucose level of 178, creatinine of 1.04, potassium of 3.7, sodium of 138, Blood urea nitrogen (BUN) of 17. Hemoglobin A1C was 8.5. Lipid panel showed a total cholesterol of 187, high density lipoproteins (HDL) of 43, low density lipoproteins (LDL) of 153, and triglycerides of 180. Thyroid stimulating hormone (TSH) was 6.4 and Thyroxine (T4) was 0.8. BNP was mildly elevated at 148.

The patient was ultimately diagnosed with primary hypertension (I10), uncontrolled type two diabetes (E11.65), and mixed hyperlipidemia (E78.2). The patient's Atorvastatin was increased from 20 mg to 40 mg in the presence of hyperlipidemia. Lisinopril was increased from 20 mg to 40 mg daily given hypertension. Metformin switched to extended release Metformin 1000 mg daily due to recent gastrointestinal upset. Patient instructed to track her blood pressures and her blood glucose levels and bring her logs with her at the next visit. The importance of medication compliance was discussed at length with the patient. Education was provided about how uncontrolled diabetes and hypertension are independent risk factors for the development of heart failure. The rate of mortality and morbidity were discussed with the patient, along with complexity of managing patient's symptoms upon diagnoses. If the patient continues along this path of poor disease management, she will most likely be diagnosed with heart failure at some point in her life. Given her history of poor medication adherence and symptom monitoring, the

patient's heart failure would likely be difficult to manage given it would require a strict medication regimen, daily weights, daily symptom monitoring, and dietary restrictions. To prevent frequent ER visits and 30 day readmissions, this patient would benefit from the technologic advances that allow frequent monitoring of cardiopulmonary filling pressures by the provider, allowing for timely intervention.

Literature Review

Fluid overload is the most common cause of hospitalization related to heart failure. The changes in fluid volume status are commonly monitored by daily weights and the presence of edema reported by patients to clinicians. However, when these clinical signs do present it is often when the patient is already decompensated enough to where they need to be admitted to the hospital. The technologic advances in heart failure management can now help clinicians take on a more proactive and preventative method to monitoring patient's volume status and decreasing unnecessary emergency room visits and hospital admissions. (Abraham et al., 2016). Changes in pulmonary artery (PA) pressure occur very early on in the progression toward cardiac decompensation, and are a direct indicator of worsening heart failure. Early changes can often be addressed through increasing the use of various medications, thus reducing the need for ER visits and hospital admissions. The titration of diuretics at the first sign of any changes in the PA pressure can make a significant impact and prevent complications (Adamson et al., 2011).

CardioMEMS HF System is a PA pressure monitoring system that is implanted into the pulmonary artery during a simple cardiac catheterization procedure. The sensor is approximately the size of a dime and cannot be seen through the skin and will not interfere in any way with regular daily activities. The sensor comes with an electronic unit that is simply placed on the skin over the CardioMEMS device on daily basis, which then transmits the real time PA pressures

directly to the provider. The provider sets certain parameters for the PA pressures and is notified if the pressures go outside of the parameters. The provider is directly notified if the patient is outside parameters and can call the patient to instruct them to take an extra diuretic in order to decrease the PA pressure, ultimately preventing an unnecessary visit to the emergency room or a hospital admission due to heart failure exacerbations (Loh, Barbash, & Waksman, 2011).

A growing database of clinical trial data suggests that lower cardiac filling pressures are associated with a lower rate of clinical decompensation and improved use of life-saving medical therapies. Filling pressures within the heart increase as most patients decompensate, which occurs days or weeks prior to the development of any physical symptoms, changes in daily weights, or clinician examination findings that normally alert the provider or the patient that their condition is worsening (Abraham et al., 2016).

The CHAMPION trial utilized the principles of heart failure pathophysiology that were discovered by previous trials of implantable hemodynamic monitoring in patients with heart failure. One observation that was utilized in the CHAMPION trial included the fact that patients with persistently high filling pressures had a high risk of hospital admission. Furthermore, treating the elevated pressures and consistently keeping the pressures at lower levels reduced the risk of hospital admissions. Another hemodynamic characteristic of heart failure includes the idea that persistent increases in pulmonary artery pressures over time often indicated a significant risk of decompensation and the need for intensive inpatient care. These hemodynamic features are similar between patients with heart failure with reduced or preserved ejection fraction (Abraham et al., 2016). These important characteristics of heart failure formed the groundwork for the idea that medication changes that intended to lower pulmonary artery

pressures might improve clinical stability and reduce rates of hospital admission in high risk patients (Zile et al., 2011).

The CHAMPION trial was a randomized control trial that was designed to determine if medical management of heart failure was improved with hemodynamic monitoring or if conventional methods of monitoring heart failure patients would produce the same outcomes. This landmark study involved 550 individuals at sixty-four sites throughout the United States diagnosed with NYHA functional class III heart failure. All patients had a CardioMEMS heart failure sensor implanted and were trained on how to take pulmonary artery pressures daily and how to operate the electronic device that was sent home with them. The patients were informed that all of their measurements would be automatically sent via a telephone connection to a secured internet database for the researchers to monitor. Prior to being discharged home, the patients were selected to be in the treatment group or the control group after having the device implanted. The investigators determined their heart failure management by the hemodynamic information that was provided from the CardioMEMS devices, while the control group were provided with the standard heart failure management guidelines that was based on clinical signs and symptoms versus hemodynamic monitoring. Both the control and treatment groups had follow up visits scheduled at one month, three months, six months, and then every six months for thirty-six months. Standardized guidelines were used to manage patients based on their hemodynamic numbers by classifying them as optivolemic, hypervolemic, or hypovolemic. Patients were classified as optivolemic if they had a pulmonary artery systolic pressure of 15-35 mmHg, pulmonary artery diastolic pressure 8-20 mmHg, and a pulmonary artery mean pressure 10-25 mmHg. Optivolemic status allowed the investigators to maximize dosing of medications including beta blockers, angiotensin antagonists, or aldosterone antagonists. Long

acting nitrates were also used to help improve resting and filling pressures (Adamson et al., 2011).

The overall purpose of the CHAMPION Trial was to test the hypothesis that long-term heart failure management can be enhanced by frequent remote monitoring of cardiac filling pressure by using an implanted device. The goal of the study was to determine the risks and benefits of heart failure management using an implanted hemodynamic monitor, such as the CardioMEMS system. The investigators specifically assessed how this intervention impacted heart failure related hospitalizations versus standard heart failure management (Adamson et al., 2011).

During the randomized access period (first six months of the study), the investigators had access to the pulmonary artery pressure numbers of the patients in the treatment group but not of the control group. The study showed that pulmonary artery pressure-guided heart failure management of patients in the treatment group resulted in a thirty-three percent reduction in heart failure related hospital admissions and sixteen percent reduction in all-cause hospital admission. Furthermore, the risk of dying or having a heart failure-related admission was twenty-three percent less in the treatment group versus the control group. After all participants completed their six month follow up visit, the open access period started and lasted thirty-one months. During this time, the investigators had access to PA pressure numbers in both groups; however, adjustment of therapy was no longer monitored by the protocols that were initiated during the first six months. Patients that were previously receiving guideline-directed management alone during the randomized period (first six months), now had their pulmonary artery pressure monitored during the open access period. This resulted in significant clinical improvements including a forty-eight percent reduction in heart-failure related admissions. The

risk of death or first admission to the hospital related to heart failure was forty-seven percent less for these individuals during the open access period (Abraham et al., 2016).

The study showed that hemodynamic-guided management of heart failure was superior to simply relying on standard disease management strategies of monitoring weight and symptoms. Specifically, hemodynamic-guided management of heart failure helps maintain patient stability and avoids acute decompensation, thus resulting in less heart failure-related hospital admissions (Abraham, et al., 2016). Overall, the CHAMPION trial demonstrated a significant reduction in heart failure hospitalizations in patients with New York Heart Association Class III that were managed by pulmonary artery pressure readings according to their CardioMEMS device.

Shortly after the CardioMEMS research was published, a post approval study was conducted to assess the safety and efficacy of the CardioMEMS system in a commercial setting. This post approval study was conducted at 150 sites across the United States with the purpose of analyzing the outcomes of the first 300 patients enrolled in the study during the first 6 months after having the CardioMEMS device implanted. The 300 individuals had NYHA Class III heart failure and had experienced at least one heart failure-related hospitalization within the last year who had the CardioMEMS system implanted. The study was conducted from January 2015 to March 2016. There was a total of fifty-six heart failure hospitalizations after the CardioMEMS device was implanted, which equals of rate of 0.20 events per patient for six months and 0.40 events per patient per year. These were consistent, however, slightly less than the rate observed with the treatment group of the CHAMPION trial which was 0.32 events per patient for six months. The results were also significantly lower than observed in the control group of the CHAMPION trial showing 0.44 events per patient throughout the six months. This post approval study shows that the outcome for patients that was shown in the CHAMPION trial remains

consistent in the commercial setting, displaying a reduced number of heart failure hospitalizations after the system was implanted (Raval et al., 2017).

During the same time as the previous study was being conducted, another team of researchers set out to test the use of the CardioMEMS device outside of the clinical trial setting. Data was retrospectively collected on patients from January 5th, 2015 to October 6th, 2016 at four different sites throughout Minnesota and South Dakota. The total number of all-cause hospital admissions, heart failure-related admissions, emergency department visits, and cardiology clinic visits one-year post implant of the device were compared to the number of visits one year prior to the device. There was a significant decrease in all types of visits after the CardioMEMS device was implanted with the total number of visits going from 2101 per year down to 1230 per year for all subjects at all sites. Specifically, there was a decrease in total hospital admissions, heart failure-related admissions, and emergency department visits after device implantation. However, there was not a decrease in the total number of clinic visits. A major limitation of this study is that it does not mention if there was an increased number of clinic visits as a result of monitoring PA pressures and attempting to manage the pressures prior to a visit to the ER or hospital is necessary. This study again suggested that the CardioMEMS Heart Failure System can decrease heart failure exacerbations resulting in a reduced number of ER visits and hospital admissions outside of a clinical trial setting (Davidovich et al., 2017).

The Sanford Cardiovascular Institute in Sioux Falls, SD completed a study on fifty-one individuals that had CardioMEMS devices implanted. Data was collected to determine all-cause hospital admissions, heart-failure hospitalizations, and ER visits twelve months prior to having the CardioMEMS device and implanted and twelve months after the device was implanted. After implantation of the CardioMEMS device, patients were treated with medication adjustments of

vasodilators or diuretics based on their pulmonary artery pressures without any regard to their symptoms. Prior to implant, the total all cause hospital admission rate was 180 and the number of heart failure related admission was ninety-five. During the twelve months after the CardioMEMS device was implanted, the all cause admission rate decreased to sixty-five and the heart failure related admissions decreased to sixteen. This was a sixty-four percent reduction in all cause admissions and an eighty-four percent reduction in heart failure-related admissions. The total ER visits for all causes prior to implantation of the CardioMEMS device was at an astonishing rate of 1229, while the number of heart failure related ER visits was 614. After implantation of the CardioMEMS device, the all cause ER visits was decreased by 87% down to a rate of 164. The heart failure related ER visits was reduced to a total of 118, which was an 81% reduction (Preister, Case, Deibert, & Jonsson 2017).

Another study completed a retrospective chart review of patients that were implanted with CardioMEMS devices between March 2015 to September 2016. Although the study was small with a chart review completed on only thirty-two total patients, the results were still quite significant. The researchers completed a chart review on the subjects one year prior to implantation of the CardioMEMS device in regards to the number of times they were admitted to the hospital due to complications of heart failure versus how many times they were admitted to the hospital after the CardioMEMS device was in place. Patients were followed until they had a heart transplant, a ventricular assist device placed, or until their death. Poisson regression and competing risks were used to displace the discrepancies between pre implant and post implant event rates as well as time to first admission. In the one year prior to implant, a total of thirty heart failure related admissions occurred for all of the subjects. This resulted in an average of 0.46 number of events per patient per 180 days. After the implantation of the CardioMEMS

device that directed the patient's heart failure management, there was a substantial decrease to an average of eight heart failure-related admissions. This results in an average of 0.17 events per patient per 180 days, which was a significant decrease from prior to implantation (Sauld, Pedersen, & Sulemanjee, 2017).

Researchers at a large community hospital wanted to test the hypothesis of the CHAMPION trial that implantation of the CardioMEMS device in the appropriate population (NYHA class III heart failure) can reduce the number of hospitalizations that occur as a result of heart failure. The reason behind their research was due to the concern of the cost of heart failure-related readmissions. According to the Medicare Payment Advisory Commission, the annual estimated cost of heart failure related admissions is 17.4 billion dollars (Caruso et al., 2017). Researchers at Lankenau Medical Center completed a retrospective chart review one year prior to and post implant of the CardioMEMS device. The average age of the subjects was seventy-seven, with ages ranging from fifty-three to ninety-two. Prior to device implantation, the average number of admissions per year was 2.14. The average number of admissions per year post implant decreased to 0.41. They also found that the average number of days spent in the hospital per year prior to implant was 12.2 days, while post implant the average number of days spent in the hospital per year decreased substantially to 6.05 (Caruso et al., 2017).

Rathman, Unruh, Nissley, Nissley, & Roberts (2016) completed another retrospective study that found that patients who underwent CardioMEMS implantation had a reduction in all cause hospital admissions from 3 to 1.7. The rate of heart failure related admissions also was reduced from 2 to 0.6 per year. An interesting difference with this study is that the researchers did not discount the fact that the use of the CardioMEMS system required increased intensity of heart failure management by the clinician and the heart failure program. The increased

interventions required by providers include status updates, medication changes, and test results. In fact, medication changes occurred on average at least once a week based upon hemodynamic monitoring. This study does suggest that future studies look at ways in which heart failure programs can become efficient in handling the increased interventions needed for patients with CardioMEMS in order to decrease the burden on providers while continuing to improve outcomes for heart failure patients (Rathman et al., 2016).

A study recently completed at the University of South Dakota Sanford School of Medicine researched the effects of timing on measurements of pulmonary artery pressures with the CardioMEMS device. Most patients with CardioMEMS devices send their device information in the morning. However, the researchers wanted to understand the difference in pulmonary artery pressures in the morning and afternoon with their medication use. Throughout the study, the subjects had their pulmonary artery pressures monitored in the morning and then three to five hours after medication administration. As one would expect, the pulmonary pressures were significantly lower in the afternoon after their medication had been taken. The mean morning pulmonary pressures was 23.16, while the afternoon mean pressure was 20.84, which is statistically significant. This study suggests that taking pulmonary artery pressures in the afternoon after their medication has had time to take effect is more reflective of their actual pulmonary artery pressure status versus morning readings (Anuwatworn, Sethi, Thompson, Jonsson, 2017). Furthermore, the findings of this study could potentially prevent clinicians from overcorrecting elevated pulmonary artery pressures when medication has not been taken yet and potentially decreasing unnecessary ER visits.

Learning Points

- Hemodynamic-guided management of heart failure with the CardioMEMS device is superior to simply relying on standard heart failure disease management strategies of monitoring weight and clinical signs and symptoms. Specifically, hemodynamic-guided management of heart failure helps maintain patient stability and avoids acute decompensation.
- Remote monitoring of pulmonary artery pressures by the use of the CardioMEMS system can help decrease heart failure exacerbations that lead to unnecessary ER visits and hospital admissions.
- Success with the CardioMEMS device requires significant interventions on the part of the heart failure program. Future studies need to be completed in order to streamline efficiency in order to reduce the overall burden that is placed on the clinicians while ensuring enhanced outcomes for the heart failure population with the use of the CardioMEMS device.
- Decreasing frequent heart failure related hospital admissions and ER visits with the use of the CardioMEMS system has the potential to be cost effective for patients and the United States health care system as a whole. However, more research needs to be completed regarding the true cost effectiveness of the system by comparing the cost of admissions versus the cost of CardioMEMS equipment and clinician time that is not reimbursed.

Conclusion

The research done by the CHAMPION trial as well as many post approval studies indicate that the CardioMEMS device can help prevent acute decompensation in patients with heart failure, thus decreasing unnecessary ER visits and hospital admissions. Furthermore, the literature review discussed with this case suggests decreased costs of heart failure-related admissions to our health care system as a whole as well as the decreased morbidity associated with more well controlled symptoms of heart failure. However, more studies do need to be completed to assess the burden of managing patients with CardioMEMS devices. Although the research shows that clinicians can prevent unnecessary ER visits and hospital admissions, the work of the heart failure management team increases tremendously with the use of the CardioMEMS devices. More studies need to be completed to create an efficient and cost-effective way of managing these patients with evidence based guidelines that would allow the heart failure nurses to intervene versus strictly relying on the provider to make suggestions or adjustments with medications. Although more research needs to be done, the evidence that was found is nonetheless promising for managing this complex disease process.

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