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CardioMems® device implantation reduces repeat hospitalizations in heart failure patients: A single center experience

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Abstract

Introduction: Hospital readmission for congestive heart failure remains one of the most important economic burdens on healthcare cost. The implantation of a wireless pressure monitoring device (CardioMEMS®) had led to nearly 40% reduction in readmission rates in the landmark CHAMPION trial. We aim to study the effectiveness of this wireless device in reducing heart failure admissions in a real-world setting.

Methods: This is a retrospective chart review of patients with recurrent admissions for heart failure implanted with the wireless pressure monitoring system (CardioMEMS®) at our institution. We studied the total number of all-cause hospital admissions as well as heart failure-related admissions pre- and post-implantation.

Results: A total of 27 patients were followed for 6–18 months. The total number of all-cause hospital admissions prior to device implantation was 61 admissions for all study patients, while the total number for the post-implantation period was 19, correlating with $2.26 + 1.06$ admissions/person-year prior to device implantation versus $0.70 + 0.95$ admissions/person-year post-implantation (p-value < 0.001). For heart failure-related admissions, the total number prior to device implantation was 46 compared to 9 admissions post device implantations, correlating with $1.70 + 1.07$ admissions/person-years pre-implantation versus $0.33 + 0.62$ admissions/person-years post-implantation (p-value < 0.001). This translates to 80.4% and 68.9% reduction in heart failure and all-cause admissions, respectively.

Conclusion: In a real-world setting, the implantation of a wireless heart failure monitoring system in patients with heart failure and class III symptoms has resulted in 80.4% reduction in heart failure admissions and 69% reduction in all-cause admissions.

Keywords

CardioMEMS, heart failure, rehospitalization

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Introduction

Repeat hospital admissions for congestive heart failure (CHF) continues to represent one of the most important and impactful factors on the United States healthcare system. Among Medicare patients, 27% of patients discharged with the diagnosis of CHF are readmitted to the hospital within 30 days.[1] Twenty-five percent of all-cause readmissions within 30 days and roughly 50% within six months were due to heart failure.[2,3] Improvements in outpatient management of patients with chronic heart failure are needed to address the increasing economic burden and health risks associated with readmissions to the hospital.[4] Signs and symptoms of pulmonary congestion are usually the main reasons why patients are admitted to the

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hospital.[5] Previous studies have shown that a rise in intracardiac and intrapulmonary pressures precede the onset of symptoms by several days, and even weeks.[6] The investigators in the CHAMPION trial showed that patients who were managed based on information from a wireless pressure monitoring device (CardioMEMS®) (St Jude Medical, Atlanta, GA) resulted in 37% less hospital admissions than those who were managed based on symptoms and/or clinical criteria (such as daily weight) alone, and intense monitoring through phone calls and office visits.[2]

The CardioMEMS® device is a wireless device which is implanted percutaneously into the pulmonary artery (PA). Using an electronic console in the form of a pillow, the patient transmits PA pressure readings to a secure online database, which is accessible to the managing cardiologist.

We studied patients who received the CardioMEMS® device at our institution and compared the rate of hospital admissions before and after device implantation. We sought to investigate whether the CardioMEMS® device significantly reduced the number of hospital admissions in patients with CHF in a similar fashion to the CHAMPION trial, but in a real-world setting.

Methods

We collected data on all patients in whom we implanted the CardioMEMS® device between December 2014 and January 2016 at our institute. Patients who received the device had to fulfill the criteria required to be eligible for implantation. This included patients who had New York Heart Association (NYHA) functional class III heart failure, irrespective of left ventricular ejection fraction or cause (i.e. both patients with heart failure with reduced ejection fraction (HFrEF) and those with preserved ejection fraction (HFpEF)), and at least one hospitalization for heart failure within the preceding 12 months. Twenty-seven patients met the inclusion criteria and were implanted within the time period defined above. We followed the patients till June 2016 so that the first patient implanted during study period was followed up for 18 months, and the last patient implanted was followed up for 6 months, for a total follow-up period for the entire study cohort of 6–18 months. All patients were receiving maximally tolerated guideline directed medical therapy for heart failure, which included beta blockers, angiotensin converting enzyme inhibitors (ACE-I) or angiotensin receptor blockers (ARBs), aldosterone antagonists, loop diuretics, hydralazine, and nitrates, unless they had contraindications or intolerance (Table 1). The mean pulmonary arterial and diastolic pressures were reviewed on a weekly basis and if trends of elevation were seen, patients would receive a phone call to ask about their dietary habits, salt, and water intake, or recent changes to their medications. Dietary restriction would be emphasized, and adjustment of diuretic therapy ordered if deemed necessary. The patients would be asked to come for a follow-up visit in one week if their readings showed a trend in pressure elevation. The general intention was to keep PA diastolic (PAd) pressure <20–25 mmHg; however, goals were individualized based on baseline right heart catheterization findings. These goals were based on the treating physician's best knowledge of pertinent data, including renal function and hemodynamic data such as systemic and pulmonary pressures as well as diastolic pulmonary gradient. The diastolic pressure gradient at baseline is an important parameter for consideration of a particular patient's goal for the PA diastolic pressure, as clinical decisions using CardioMEMS rely on indirect data of left ventricular filing pressure (i.e. PA diastolic, as a corollary of pulmonary capillary wedge pressure/left atrial mean pressure). Table 2 shows PA pressure readings at implantation, 1, 2, 3, and 6 months.

Table 1. Medications prior to and following implantation.

Medication	Prior to implantation (%)	Following implantation (%)
Beta blockers	92.6	85.2
ACE-I or ARBs	77.8	74.1
Spironolactone	33.3	55.6
Nitrates	22.2	29.6
Hydralazine	18.5	25.9
Diuretics	81.5	88.9

ACE-I: angiotensin converting enzyme inhibitors; ARBs: angiotensin receptor blockers.

We reported the total number of hospital admissions as well as heart failure admissions prior to implantation of the device and compared this to the same period of time we had available for follow-up, such that each patient served as their own control. For example, if we had 10 months of follow-up on a particular patient, we collected data for 10 months prior to implantation. We studied the total number of all-cause hospital admissions pre- and post-implantation as well as the number of heart failure-related admissions pre- and post-implantation. A paired Student's t-test analysis was then performed using SPSS statistical software.

Results

A total of 27 patients were included in the review. The longest follow-up period was 18 months, and the shortest was 6 months. Baseline characteristics were

Table 2. Pulmonary artery pressure readings (systolic/diastolic/mean) in mmHg.

Patient	Baseline EF (%)	At implantation	At 1 month	At 2 months	At 3 months	At 6 months
1	20	19/12/15	46/22/33	31/17/23	44/21/31	19/9/13
2	25	73/28/42	83/36/53	69/28/42	69/30/43	NT
3	30	33/18/23	28/15/20	25/10/16	32/14/21	31/13/20
4	10	56/22/38	49/21/29	42/19/28	53/26/36	52/26/36
5	15	42/22/34	41/25/33	42/26/36	43/20/30	49/25/35
6	20	25/8/15	27/5/13	29/7/16	39/12/23	29/7/15
7	30	43/28/35	58/30/41	55/24/35	49/21/31	39/16/24
8	10	45/24/30	56/26/37	50/19/33	36/7/18	NT
9	20	59/32/42	65/34/44	NT	NT	NT
10	30	31/18/22	40/24/29	44/25/31	41/24/30	37/21/27
11	20	42/24/31	36/20/25	41/24/31	44/28/34	40/23/29
12	30	39/23/29	46/26/33	45/26/32	42/22/28	34/19/24
13	15	23/11/15	26/11/15	26/11/16	31/16/21	36/24/29
14	20	53/26/36	41/21/30	56/28/40	50/27/38	42/17/27
15	20	54/29/38	56/32/42	54/32/41	52/36/43	NT
16	15	70/29/47	54/18/34	47/13/28	NT	64/27/43
17	25	61/35/44	56/30/40	65/34/46	NT	NT
18	45	83/45/60	59/33/43	54/31/39	57/31/41	NT
19	65	82/53/64	61/39/46	75/46/57	71/41/51	NT
20	30	62/20/38	36/11/20	36/12/21	45/18/28	52/17/29
21	25	44/17/27	30/13/20	50/21/32	44/21/31	36/14/22
22	55	58/32/43	69/39/52	40/21/27	54/21/38	56/28/38
23	35	74/33/52	73/40/53	87/33/53	70/26/41	53/19/32
24	20	65/21/37	65/21/36	NT	NT	52/21/32
25	10	57/32/42	48/25/34	62/35/46	60/34/44	67/35/49
26	30	66/33/47	70/36/49	51/22/35	68/33/48	64/31/46
27	60	49/29/38	41/23/31	54/33/42	47/23/32	48/24/33

NT: no transmission; EF: ejection fraction.

Table 3. Baseline characteristics.

Characteristic	Entire group (n=27)
Age (years)	67 ± 12 years
Male	14 (52%)
African American	16 (59%)
HFpEF	3 (11%)
HFrEF	24 (89%)
Hypertension	27 (100%)
Diabetes mellitus	17 (63%)
Hyperlipidemia	26 (96%)
Coronary artery disease	16 (59%)
Atrial fibrillation	11 (41%)
Stroke	6 (22%)
Obstructive sleep apnea	7 (26%)
Chronic kidney disease Stage 2	3 (11%)
Chronic kidney disease Stage 3	10 (27%)
Chronic kidney disease Stage 4	2 (7%)

HFrEF: heart failure with reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction.

collected for all patients (Table 3). The number of males and females were almost equal. Fifty-nine percent of the patients were African American. The majority of patients were on clopidogrel and/or aspirin. Some patients were on warfarin or a direct oral anticoagulant agent. Eighty-nine percent had systolic heart failure, 41% had atrial fibrillation, and 100% had hypertension (Table 3). Three of the 27 patients died of causes not related to the device itself or implantation procedure. None of the study patients had complications related to device implantation, including vascular complications, infections, pulmonary hemorrhage, or other major complications.

The total number of all-cause hospital admissions for all 27 patients prior to device implantation was 61 admissions, while the total number for the post-implantation period was 19 for those same patients. The mean all-cause admissions per month prior to device implantation was 0.196 ± 0.096; post-implantation mean monthly admission rate was 0.073 ± 0.104 (p-value < 0.001). This correlates with an all-cause hospital admission event rate of 2.26 ± 1.06 admissions/person-year prior to device implantation and 0.70 ± 0.95 admissions/person-year post-implantation (p-value < 0.001). For heart-failure-related admissions, the total number of admissions prior to device implantations was 46, compared to nine admissions post-device implantation. Mean heart failure admissions per month prior to

device implantation was 0.150 ± 0.095 compared to 0.041 ± 0.092 post-implantation (p-value < 0.001) (Table 4 and Chart 1). This correlates with a heart-failure-related admission event rate of 1.70 ± 1.07 admissions/person-years prior to implantation versus 0.33 ± 0.62 admissions/person-years post-implantation (p-value <0.001). This translates to an 80.4% reduction in heart failure admissions and a 68.9% reduction in all-cause admissions.

Discussion

CHF carries with it an immense economic impact on the American healthcare system. In 2012, heart failure cost the American healthcare system roughly 31 billion dollars (accounting for both direct and indirect costs). Furthermore, the AHA estimates that the total medical costs for heart failure are projected to increase to 70 billion dollars by 2030.[7] Additionally, the implications for morbidity and mortality are substantial. Previous studies have shown decreased survival of patients with heart failure after each admission to the hospital.[8,9] Setoguchi et al. showed the median survival after first, second, third, and fourth hospitalization to be 2.4, 1.4, 1.0, and 0.6 years, respectively.[8] The tremendous effect on quality of life is another consideration, with patients often limited in activity due to symptoms of fatigue, dyspnea, and fluid accumulation.[10]

Medical therapy is a key element of treatment of patients with heart failure with preserved or reduced ejection fraction. The ACCF/AHA executive summary published in 2013 made several recommendations for medications to use to impact heart failure mortality (for example, ACE-I or ARBs), beta blockers, aldosterone receptor antagonists, hydralazine, and isosorbide dinitrate when appropriate).[11] The focused update added sacubitril/valsartan to the recommended medications as a substitute to ACEI or an ARB. Ivabradine was also cited as being potentially beneficial to reduce hospitalizations.[12] Despite recent numerous advances in heart failure therapies in the past three decades, there remains an unmet need for adequate treatment and monitoring of heart failure, with a potential to reduce the associated mortality and morbidity.

Table 4. Study results.

	Total number of pre-implantation	Admissions per month pre-implantation	Admissions per person-year pre-implantation	Total number of post-implantation	Admissions per month post-implantation	Admissions per person-year post-implantation	Percent reduction
All-cause admissions	61	0.196	2.36	19	0.073	0.87	68.9
Heart failure-related admissions	46	0.150	1.78	9	0.041	0.49	80.4

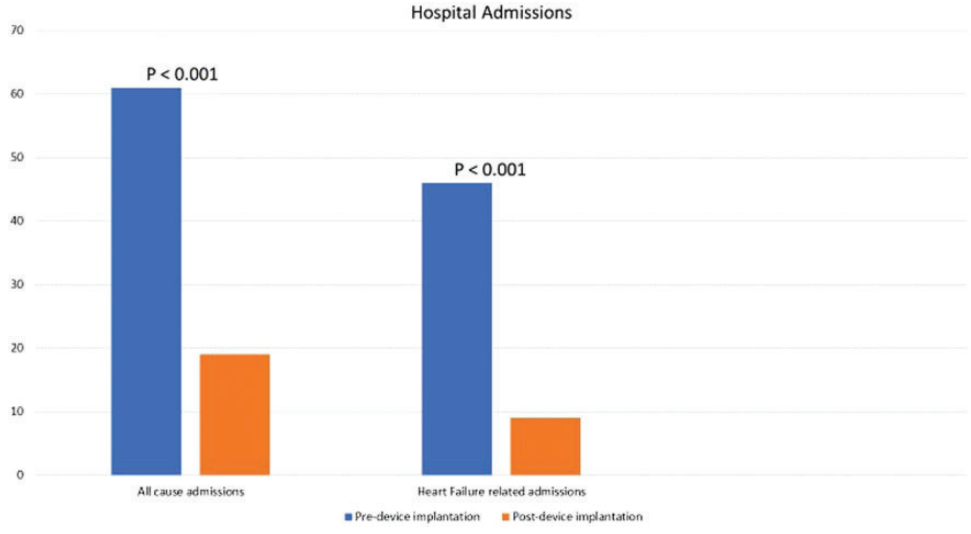

Chart 1. Comparison between number of all-cause hospital admissions and heart failure-related admissions pre- and post-device implantation.

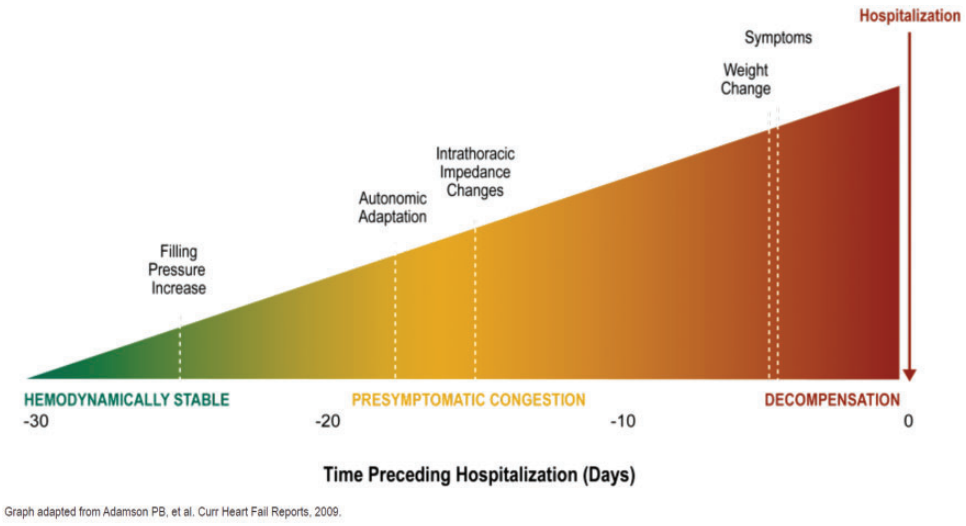

Figure 1. Filling pressures increase days before symptoms of heart failure are felt by patients.

There have been a number of attempts in the past to impact CHF prognosis in an outpatient setting by monitoring through various methods. The TELE-HF trial and the TIM-HF trial both showed no significant difference between the telemonitoring group (via monitoring of weight and blood pressure) and the control group in re-hospitalization rates and death.[13,14] In addition, several studies have shown lack of reliability of intra-thoracic impedance as an indicator of volume status. The DOT-HF trial showed increased CHF hospitalization without improvement in mortality.[15] To date, remote PA pressure monitoring is the only significant intervention that reduced repeat hospitalizations. The CHAMPION trial showed a significant reduction in heart failure hospitalizations, shorter length of stay, and improvement in quality of life in patients undergoing ambulatory PA pressure monitoring with a CardioMems device.[4] These findings have been confirmed in subsequent studies.[16,17] Cardiac filling pressures increase several days before symptoms can be reported by patients. This allows the clinician to make therapeutic changes early, which can prevent decompensation and admission to the hospital (Figure 1). While no device-related complications were incurred during our study, potential complications which have been described include PA injury and hemoptysis, sensor failure/malfunction, device embolization, device thrombosis and pulmonary embolism, access site-related bleeding and infection, and death.[18]

Our study showed a significantly lower number of hospital admissions, whether all-cause or heart failure-related, after CardioMEMS® device implantation compared to the period prior to device implantation in patients with both HFpEF and HFrEF. The population we studied was roughly balanced for gender as well as race (African Americans/Caucasians), whereas the CHAMPION trial included mostly Caucasian men.[4] Despite the population differences, our results are concordant with and potentially better than the results of the CHAMPION trial in a real-world setting, confirming our hypothesis. Patients who received the device are usually monitored by the practice of the implanting physician with weekly reports (at our institution) carefully reviewed by the patient's cardiologist. If the treating cardiologist detects a trend towards increasing diastolic PA pressures, the patient is contacted and either asked to come to the clinic for a visit, or his/her medications are adjusted to lower the PAd to the patient-specific goal (e.g. increasing the dosage of a diuretic or making a change to any other heart failure therapies). In some instances, management included simple dietary advice and salt restriction after dietary indiscretions.

Interestingly, we observed a positive impact of the implanted CardioMEMS device on the patient's overall clinical status completely unrelated to the device itself or its monitoring activity. The mere implantation of the device was frequently associated with better compliance with prescribed medications, dietary restrictions and scheduled office appointments. This phenomenon, which we termed "pseudo-placebo effect" (Hawthorne effect), was simply related to the patients significantly improving their diligence and compliance with the prescribed lifestyle modification and medication changes, as a result of their awareness of them being monitored closely.

Conclusion

Hospital readmissions for patients with CHF have been an area of significant interest for both physicians treating them and for hospitals. The national average for

30-day readmissions rate is 22.7%.[19] Medicare's Hospital Readmissions Reduction program penalizes hospitals that have above average all-cause readmissions within 30 days following heart failure discharge.

Our study was a real-life single center experience that was concordant with the CHAMPION trial findings with substantial improvement in the overall trial result, specifically 80.4% reduction in heart failure admissions and 69% reduction in all-cause admissions, as is being reported by several centers across the United Stated with high volume implants.[16,17] This device continues to show an excellent safety profile with a significantly positive impact on heart failure admissions for patients with preserved or reduced ejection fraction. Further, carefully designed and adequately powered studies are needed to confirm the suspected (and expected) secondary benefit in mortality.

Limitations

Our study has many limitations:

1. It included 27 patients which is relatively a small number of patients and might not reflect same outcomes at higher volume centers.
2. Study cohort was followed for 6–18 months, which is relatively a short duration of follow-up.
3. Eighty-nine percent of study cohort had HFrEF, which might not represent the actual prevalence of heart failure subtypes among the general population.

Contributorship

NoneMEMS.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

Ethical approval for this study was obtained from The Institutional Review Board at Providence Providence-Park Hospitals (www.Irbnet.org). IRB approval number: 912678-1.

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Guarantor

None.

Informed consent

Waiver of Informed consent was approved by the above IRB because this waiver will not adversely affect the rights and welfare of the subjects; the research could not be practicably carried out without the waiver. The protected health information involves no more than minimal risk to the subjects. The PHI was stored and transmitted with password protected, encrypted drives and was kept in locked cabinets. The PHI was not reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted. The physical data were shredded and/or electronic data were deleted at the end of the research.

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