Impact of CardioMEMS device placement on lifestyle modifications: a “pseudo-placebo” effect beyond the expected?

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Abstract

Introduction: Congestive heart failure is a leading cause of cardiovascular mortality and morbidity in the United States and places a significant economic burden on the healthcare system. The CHAMPION trial showed significant reductions in heart failure hospitalizations and length of stay as well as improvements in quality of life among patients who underwent implantation of the CardioMEMS device (CardioMEMS Inc., Atlanta, GA, USA). While the benefits of the device have been well demonstrated, we explored the “pseudo-placebo” effect of device placement on patients’ lifestyle modifications.

Methods: Thirty patients with the CardioMEMS device were contacted for a follow-up survey that included questions about lifestyle modifications, symptomatic and dietary improvement, increased physical activity, and changes in their cardiac medication regimen.

Results: Dyspnea improved in 57% of patients, 70% of patients improved their diet, and 43% increased their physical activity. Only 7% of patients found it difficult to transmit the data.

Discussion: The CHAMPION trial showed numerous benefits for patients who underwent CardioMEMS device placement. In our study, we found that device placement also resulted in a “pseudo-placebo” effect with most patients making positive lifestyle modifications.

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Keywords
Congestive heart failure, pulmonary artery pressure monitoring, CardioMEMS, lifestyle modifications, symptom improvement, quality of life

Introduction
Congestive heart failure (CHF) is one of the top causes of cardiovascular mortality and morbidity in the United States and causes a significant economic burden. Although the initial hospitalization may be costly, subsequent health care dollars are spent on repeat hospitalizations. This has prompted a number of quality measures, payment incentives, and penalties by payers to limit repeat hospitalizations. Approximately 3.4 million encounters for outpatient care of heart failure add to the health care cost burden, while roughly one-quarter of discharged patients are readmitted within 30 days.1,2 Readmissions are a common problem in patients with heart failure, particularly in patients with low socioeconomic status.3 An early cardiology consultation while the patient is in the emergency room was found to be associated with a decrease in re-hospitalization and health care costs for patients with acute decompensated heart failure.3 Another strategy to help reduce readmission rates is a post-discharge follow-up within 7 days, which decreased the risk of 30-day readmission.4 Furthermore, a quality improvement program using an electronic medical record-based approach was also found to significantly reduce 30-day readmission rates.5

More recently, the CHAMPION trial showed a significant reduction in heart failure hospitalizations, shorter length of stay, and improvement in quality of life among patients undergoing ambulatory pulmonary artery (PA) pressure monitoring with the implanted CardioMEMS device (CardioMEMS Inc., Atlanta, GA, USA).6 The lower rate of hospitalizations was associated with a $7,433 6-month comprehensive heart failure cost reduction.7 In another study, the CardioMEMS device was found to have a cost-effectiveness ratio of $44,832 per quality-adjusted life year.8 Elevated diastolic PA pressure is associated with a high risk of hospitalization and mortality, and patients with implantable hemodynamic technology were found to have lower PA pressures.9 In this study, we sought to identify potential lifestyle changes of patients with CardioMEMS device placement and whether such a technologically advanced device is easy to use for patients. As a corollary, we aimed to identify potential mechanisms of significant reduction of heart failure admission by the device beyond just the medication changes, resulting in a possible “pseudo-placebo” effect.

Methods
The study protocol was approved by the Providence Hospital Institutional Review Board (IRB no. 912678). Verbal consent for the survey was obtained prior to the survey; written consent for the procedure was obtained prior to the procedure as it was medically indicated.

Patients who underwent CardioMEMS device placement were contacted for a follow-up survey. The survey was
conducted over the telephone and included questions about lifestyle changes after device placement, improvement in dyspnea, increased physical activity, improved diet, and changes in the cardiac medication regimen. The patients were also asked if they were contacted by their cardiologist after device placement and about the ease of transmitting data using the provided equipment. The patients’ responses were recorded and tabulated (Table 1). The period from device placement to contact for the survey varied widely (maximum of 18 months). Patients were not informed of the survey at the time of device implantation because the procedure itself is considered a treatment and the survey protocol was developed at a later time. Consent was obtained from the patients prior to the survey.

**Results**

In total, 40 patients who underwent CardioMEMS device placement were identified, and 30 of them were able to be contacted for a follow-up survey. Of the 30 patients surveyed, 57% (17/30) stated that their dyspnea had improved (Table 1).

Table 1. Survey results

| Question                                                                 | Yes | No |
|------------------------------------------------------------------------|-----|----|
| Have you received phone calls from your doctor regarding your device?   | 15  | 15 |
| Has your cardiologist changed your heart medications since you received the device? | 13  | 17 |
| Have you made any changes to your lifestyle since you received the device? | 10  | 20 |
| Has your dyspnea improved since you received the device?                | 17  | 13 |
| Have you made improvements to your diet since you received the device?  | 21  | 9  |
| Have you increased your physical activity since you received the device? | 13  | 17 |
| How would you describe using the equipment to transmit the numbers as instructed? | 21  | 7  |

Although only 33% (10/30) of patients initially stated that they had made lifestyle changes after undergoing CardioMEMS device placement, when asked specifically, 70% (21/30) of patients stated they had improved their diet and 43% (13/30) of patients had increased their physical activity. In total, 50% (15/30) of patients reported receiving a phone call from their cardiologist, and 43% (13/30) of patients stated that their cardiologist had changed their medications. Finally, 70% (21/30) of patients stated that it was easy to use the provided equipment to transmit data, 23% (7/30) found it acceptable, and only 7% (2/30) found it difficult to transmit the data.

**Discussion**

Because of the significant health care burden of heart failure hospital readmissions, numerous strategies have been employed by physicians, health care organizations, and third-party payers to help reduce the readmission rates. Such strategies include cardiology consultations in the emergency room, earlier post-hospital discharge follow-up with the cardiologist, lifestyle modifications, evidence-based
medical treatment, and CardioMEMS device placement. As seen by our results, the implantation of a CardioMEMS device resulted in positive lifestyle modifications in most of the patients. The largest perceived benefit of remote PA pressure monitoring is that it allows physicians to make adjustments to a patient’s medication regimen (mainly diuretics), helping to reduce the risk of hospital admission for decompensated heart failure. The hospital readmission data from CHF exacerbation was reported in another study that is under submission at another location at this time.

We found that half of our patient population had been directly contacted by their cardiologist and almost as many had their medication regimen adjusted based on the PA pressure readings. Interestingly, undergoing device placement resulted in the added benefit of the majority of patients improving their diet and nearly as many increasing their physical activity. Patient’s adherence to transmitting measurements may have also been improved by the frequent encouraging voice messages patients receive for sending data along with reminders for missing transmissions. Furthermore, the well-known Hawthorne effect (a “pseudo-placebo” effect) is seen in many social science studies, wherein the participants are aware that an observer is present, which subsequently leads to a greater impact than would otherwise have occurred. In this scenario, such an effect is an added benefit because patients may be more compliant with their diet and medication regimens if they are aware that their physician is monitoring their objective data. Physicians can of course choose to set thresholds for patients’ transmissions; for example, patients can be sent reminders if no transmissions have been sent for 3, 5, or 7 days, the period being flexible based upon the patient’s and physician’s preference.

Finally, as technology has become more prevalent in most aspects of everyday life, only a few patients found it challenging to transmit the data; the vast majority of patients were able to do so without any difficulty. These patients encompassed a wide range of socioeconomic statuses and education levels. With frequent monitoring of objective data resulting in an almost real-time adjustment of medication regimens, improved diet adherence, and positive patient behavioral modifications, CardioMEMS device placement has become not just an effective means to monitor PA pressure in patients with CHF and help reduce hospital readmissions but also a way to substantially impact patients’ lives by encouraging beneficial lifestyle modifications with a simple-to-use device.

Although this was a small survey-based study, it has valuable implications. Our study shows the impact of device placement on patients beyond the intended consequences. Most patients improved their diet after device placement, and nearly half of the patients were exercising more frequently. This is an added benefit of PA pressure monitoring devices that could lead to more widespread use of the technology and eventually reduce the hospital admissions for CHF exacerbation as patients continue to make positive lifestyle modifications after device placement.

Declaration of conflicting interest
The authors declare that there is no conflict of interest.

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