JACC: HEART FAILURE
VOL. 4, NO. 5, 2016

ISSN 2213-1779/$36.00
PUBLISHED BY ELSEVIER
http://dx.doi.org/10.1016/j.jchf.2015.12.015

Cost-Effectiveness of Implantable Pulmonary Artery Pressure Monitoring in Chronic Heart Failure

Alexander T. Sandhu, MD,[a,b,c] Jeremy D. Goldhaber-Fiebert, PhD,[b] Douglas K. Owens, MD, MS,[a,b] Mintu P. Turakhia, MD, MAS,[a,c] Daniel W. Kaiser, MD,[a] Paul A. Heidenreich, MD, MS[a,c]

ABSTRACT

OBJECTIVES This study aimed to evaluate the cost-effectiveness of the CardioMEMS (CardioMEMS Heart Failure System, St Jude Medical Inc, Atlanta, Georgia) device in patients with chronic heart failure.

BACKGROUND The CardioMEMS device, an implantable pulmonary artery pressure monitor, was shown to reduce hospitalizations for heart failure and improve quality of life in the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) trial.

METHODS We developed a Markov model to determine the hospitalization, survival, quality of life, cost, and incremental cost-effectiveness ratio of CardioMEMS implantation compared with usual care among a CHAMPION trial cohort of patients with heart failure. We obtained event rates and utilities from published trial data; we used costs from literature estimates and Medicare reimbursement data. We performed subgroup analyses of preserved and reduced ejection fraction and an exploratory analysis in a lower-risk cohort on the basis of the CHARM (Candesartan in Heart failure: Reduction in Mortality and Morbidity) trials.

RESULTS CardioMEMS reduced lifetime hospitalizations (2.18 vs. 3.12), increased quality-adjusted life-years (QALYs) (2.74 vs. 2.46), and increased costs ($176,648 vs. $156,569), thus yielding a cost of $71,462 per QALY gained and $48,054 per life-year gained. The cost per QALY gained was $82,301 in patients with reduced ejection fraction and $47,768 in those with preserved ejection fraction. In the lower-risk CHARM cohort, the device would need to reduce hospitalizations for heart failure by 41% to cost <$100,000 per QALY gained. The cost-effectiveness was most sensitive to the device's durability.

CONCLUSIONS In populations similar to that of the CHAMPION trial, the CardioMEMS device is cost-effective if the trial effectiveness is sustained over long periods. Post-marketing surveillance data on durability will further clarify its value. (J Am Coll Cardiol HF 2016;4:368–75) © 2016 by the American College of Cardiology Foundation.

The treatment of heart failure costs more than $20.9 billion in total health care expenditures (1). Most of these costs are incurred from treating clinical decompensations of patients with heart failure that result in more than 1 million hospital admissions annually (1,2). The CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) trial, a randomized, single-blinded, multicenter trial, investigated the use of an implantable, wireless pulmonary artery pressure monitoring system to decrease hospitalizations related to heart failure (3). In this study, 550 patients with New York Heart Association (NYHA) functional class III heart failure and a hospitalization for heart failure within the previous year underwent

From the [a]Veterans Affairs Palo Alto Health Care System, Palo Alto, California; [b]Center for Health Policy and Center for Primary Care and Outcomes Research, Department of Medicine, Stanford University, Stanford, California; and the [c]Department of Medicine, Stanford University School of Medicine, Stanford, California. This study was also supported in part by the Department of Veterans Affairs Quality Enhancement and Research Initiative 04-326. Drs. Sandhu, Owens, Turakhia, Kaiser, and Heidenreich were supported by the Department of Veteran Affairs. Dr. Goldhaber-Fiebert is supported by a National Institute of Health (NIH) NIA Career Development Award (K01 AG037593-01A1: PI: Goldhaber-Fiebert). Dr. Turakhia has consulted for St. Jude Medical, Medtronic, and Precision Health Economics. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received October 1, 2015; revised manuscript received December 11, 2015, accepted December 22, 2015.

pulmonary artery sensor implantation. Patients were randomized to a treatment group in which providers were given access to the pressure readings or a control group in which the provider could not access the pressure readings. The treatment group was found to have fewer hospitalizations for heart failure and improved quality of life.

Newer management strategies such as CardioMEMS (CardioMEMS Heart Failure System, St. Jude Medical Inc., Atlanta, Georgia) that reduce costly hospitalizations for heart failure may decrease the substantial clinical and economic burden of heart failure. However, the high device cost (listed as $17,750 with Medicare) raises questions regarding its value (4). We performed an independent analysis of the cost-effectiveness of this device in a cohort on the basis of the trial, as well as in subgroups defined by ejection fraction. Additionally, we performed an exploratory analysis of the device in an alternative, larger trial-based cohort of patients with heart failure by using the CHARM (Candesartan in Heart failure: Reduction in Mortality and Morbidity) trials (5).

SEE PAGE 376

METHODS

DECISION MODEL. We developed a Markov model to determine the cost-effectiveness of the CardioMEMS device compared with usual care from a societal perspective in a CHAMPION trial cohort over a lifetime horizon. This cohort included adults (average age 62 years) with NYHA functional class III heart failure who were hospitalized within 1 year with preserved ejection fraction (21.7%) or reduced ejection fraction (78.3%). We used hospitalization and mortality rates from the CHAMPION trial (3). We performed subgroup analyses of cohorts with reduced ejection fraction (average age 60 years) and with preserved ejection fraction (average age 66 years) from the CHAMPION trial by using overall trial event rates and subgroup-specific rate ratios for each event from trials with larger sample sizes than CHAMPION (6–9). Subgroup-specific device efficacy was extracted from the CHAMPION trial (3).

In the model, patients had CardioMEMS device placement at the outset, which could involve a procedural complication or device deployment failure. In subsequent monthly intervals, patients could experience hospitalizations for heart failure, hospitalizations not related to heart failure, device complications, and all-cause mortality (Online Figure 1). Patients had an increased mortality risk during hospitalization for heart failure and for 2 months post-hospitalization. The model followed all patients over their lifetimes. We matched the mortality rates over the mean duration of the trial for the control arm of the CHAMPION trial (17 months). After the trial period of 17 months, all event rates are extrapolated. We extrapolated an age-based increase in overall mortality from a previous retrospective analysis (10).

RATE OF HOSPITALIZATION FOR HEART FAILURE AND EFFICACY OF THE CardioMEMS DEVICE. We matched the trial rates of hospitalizations secondary to heart failure for each cohort. We modeled a declining rate of hospitalization over the CHAMPION trial duration. We modeled the CardioMEMS reduction in the rate of hospitalizations for heart failure on the reduction over the entire trial (hazard ratio [HR]: 0.63). We assumed that preventing a hospitalization prevented inpatient and 2-month post-hospitalization increases in mortality (11–13). We did not model any additional CardioMEMS-associated mortality reduction in the base case. For our base case, we assumed that the benefit of the CardioMEMS device would continue lifelong and examined shorter durations in sensitivity analyses.

CardioMEMS DEVICE EVENTS. We modeled periprocedural complications as a composite of the procedure-related serious adverse events and major bleeding during the 30-day post-procedure anticoagulation period (3). We additionally modeled procedural placement failure and CardioMEMS-related serious adverse events that occurred after the initial month.

QUALITY OF LIFE AND COSTS. We included quality of life estimates for the patient's baseline health, the use of the CardioMEMS device, hospitalizations, and complications by using utilities. We calculated utility values by converting the 6-month Minnesota Living with Heart Failure (MLWHF) questionnaire score for the control arm in the CHAMPION trial into EQ-5D scores (14). The difference-in-difference in EQ-5D score between groups from baseline to 6 months was applied as the quality of life benefit for the CardioMEMS device for the first year. The difference-in-difference between groups from baseline to 12 months was applied thereafter. The 6-month differences were used for the entire first year because 226 of 550 patient scores were missing at 12 months. Disutilities were applied for the initial procedure, hospitalizations, and complications. Comparisons of patient utility during and after a hospitalization for heart failure showed an 11% lower utility during hospitalization, for a decrement of approximately 3 days (15). These assumptions were tested in

ABBREVIATIONS AND ACRONYMS

NYHA = New York Heart Association

QALY = quality-adjusted life year