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ORIGINAL INVESTIGATIONS

Ambulatory Hemodynamic Monitoring Reduces Heart Failure Hospitalizations in "Real-World" Clinical Practice

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ABSTRACT

BACKGROUND In the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association [NYHA] Functional Class III Heart Failure Patients) trial, heart failure hospitalization (HFH) rates were lower in patients managed with guidance from an implantable pulmonary artery pressure sensor compared with usual care.

OBJECTIVES This study examined the effectiveness of ambulatory hemodynamic monitoring in reducing HFH outside of the clinical trial setting.

METHODS We conducted a retrospective cohort study using U.S. Medicare claims data from patients undergoing pulmonary artery pressure sensor implantation between June 1, 2014, and December 31, 2015. Rates of HFH during pre-defined periods before and after implantation were compared using the Andersen-Gill extension to the Cox proportional hazards model while accounting for the competing risk of death, ventricular assist device implantation, or cardiac transplantation. Comprehensive heart failure (HF)–related costs were compared over the same periods.

RESULTS Among 1,114 patients receiving implants, there were 1,020 HFHs in the 6 months before, compared with 381 HFHs, 139 deaths, and 17 ventricular assist device implantations and/or transplants in the 6 months after implantation (hazard ratio [HR]: 0.55; 95% confidence interval [CI]: 0.49 to 0.61; $p < 0.001$). This lower rate of HFH was associated with a 6-month comprehensive HF cost reduction of $7,433 per patient (IQR: $7,000 to $7,884), and was robust in analyses restricted to 6-month survivors. Similar reductions in HFH and costs were noted in the subset of 480 patients with complete data available for 12 months before and after implantation (HR: 0.66; 95% CI: 0.57 to 0.76; $p < 0.001$).

CONCLUSIONS As in clinical trials, use of ambulatory hemodynamic monitoring in clinical practice is associated with lower HFH and comprehensive HF costs. These benefits are sustained to 1 year and support the "real-world" effectiveness of this approach to HF management. (J Am Coll Cardiol 2017;69:2357–65) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

CMS = Centers for Medicare and Medicaid Services

HF = heart failure

HFH = heart failure hospitalization

PAP = pulmonary artery pressure

VAD = ventricular assist device

Despite considerable progress in the development of effective medical therapy, patients with chronic heart failure (HF) remain at high risk for recurrent hospitalization and death (1). In the Medicare-eligible population, roughly 1 in 4 patients are readmitted within 30 days of hospitalization, and nearly one-half are readmitted within 6 months (2). Most of these hospitalizations are related to congestive exacerbations driven by a progressive rise in intracardiac filling pressures, independent of ejection fraction or etiology (3–7).

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Data from trials of implantable hemodynamic monitoring demonstrate that in many (although not all) cases, filling pressures rise weeks in advance of symptoms sufficient to trigger clinical attention, suggesting a window of opportunity to intervene to prevent heart failure hospitalizations (HFHs) with early detection of congestion (8). Although several methods for remote monitoring of HF patients have been considered, approaches that focus on weight (9–11) and changes in device-based diagnostics (such as intrathoracic impedance [12]) have not been effective in reducing hospitalization rates. In contrast, HF management guided by longitudinal access to pulmonary artery pressures (PAPs) was associated with substantial reduction in rates of HFH in the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in New York Heart Association [NYHA] functional Class III Heart Failure Patients) trial. These benefits persisted over the full duration of randomized follow-up (13), were consistent in patients with both preserved and reduced ejection fraction (14) as well as Medicare-eligible subjects (15), and were tightly linked to the achieved reduction in PAP with diuretic agents and other guideline-directed pharmacological therapies (16). Based on these observations, in May 2014, the U.S. Food and Drug Administration (FDA) approved the CardioMEMS HF System (Abbott, Sylmar, California) as an approach to reducing HFH in patients with chronic HF, New York Heart Association functional class III functional capacity, and a hospitalization for HF management in the year prior to implantation.

Therapeutic efficacy of an intervention in select populations managed within the tightly regulated framework of a clinical trial may not accurately represent real-world effectiveness during general use in clinical practice. The early experience of hemodynamic-guided HF management does suggest that the PAP reductions achieved with hemodynamic monitoring in the "real world" are comparable to those observed during the CHAMPION trial (17). It remains unclear, however, whether these pressure reductions have meaningfully influenced the rate of HFH in implanted patients. We examined publicly available administrative claims data from the U.S. Centers for Medicare & Medicaid Services (CMS) to compare the rates of HFH and the costs associated with HF care in the periods before and after PAP sensor implantation.

METHODS

DATA SOURCE AND IDENTIFICATION OF THE COHORT. We conducted a retrospective cohort study using CMS administrative claims data from the Standard Analytic File to evaluate health care utilization in U.S. fee-for-service Medicare beneficiaries receiving a PAP sensor implant during the period following FDA approval for commercial use (from June 1, 2014, onward). These data include Part A inpatient claims, Part B outpatient claims, and the associated denominator files (18). The inpatient and outpatient files contain institutional claims with International Classification of Diseases-Ninth or -Tenth Revision-Clinical Modification diagnosis codes, procedure codes, and reimbursement associated with inpatient stays or ambulatory visits. The denominator files include unique deidentified patient identifications, age, sex, geographic location, race or ethnicity, date of death (if present), and information about program eligibility and Medicare insurance enrollment.

PAP sensor implants were identified by inpatient claims associated with the procedure codes 38.26, 02HQ30Z, or 02HR30Z and outpatient claims associated with Current Procedural Terminology codes C9741 and C2624 (Online Table 1). As Medicare data were available through June 30, 2016, only implants on or before December 31, 2015, were included to ensure a minimum of 6 months of potential follow-up. The cohort was further limited to patients with continuous, fee-for-service (non-health maintenance organization) Medicare insurance enrollment (Parts A and B) for at least 6 months before and after implantation, retaining those who died at any time post-implant (6-month cohort). A subset of patients who received

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