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FOCUS ISSUE: CONTEMPORARY MANAGEMENT OF HEART FAILURE

Interventions Linked to Decreased Heart Failure Hospitalizations During Ambulatory Pulmonary Artery Pressure Monitoring

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ABSTRACT

OBJECTIVES This study sought to analyze medical therapy data from the CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in Class III Heart Failure) trial to determine which interventions were linked to decreases in heart failure (HF) hospitalizations during ambulatory pulmonary artery (PA) pressure-guided management.

BACKGROUND Elevated cardiac filling pressures, which increase the risk of hospitalizations and mortality, can be detected using an ambulatory PA pressure monitoring system before onset of symptomatic congestion allowing earlier intervention to prevent HF hospitalizations.

METHODS The CHAMPION trial was a randomized, controlled, single-blind study of 550 patients with New York Heart Association functional class III HF with a HF hospitalization in the prior year. All patients undergoing implantation of the ambulatory PA pressure monitoring system were randomized to the active monitoring group (PA pressure-guided HF management plus standard of care) or to the blind therapy group (HF management by standard clinical assessment), and followed for a minimum of 6 months. Medical therapy data were compared between groups to understand what interventions produced the significant reduction in HF hospitalizations in the active monitoring group.

RESULTS Both groups had similar baseline medical therapy. After 6 months, the active monitoring group experienced a higher frequency of medications adjustments; significant increases in the doses of diuretics, vasodilators, and neurohormonal antagonists; targeted intensification of diuretics and vasodilators in patients with higher PA pressures; and preservation of renal function despite diuretic intensification.

CONCLUSIONS Incorporation of a PA pressure-guided treatment algorithm to decrease filling pressures led to targeted changes, particularly in diuretics and vasodilators, and was more effective in reducing HF hospitalizations than management of patient clinical signs or symptoms alone. (J Am Coll Cardiol HF 2016;4:333–44)

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ABBREVIATIONS AND ACRONYMS

AA = aldosterone antagonist

ACEI = angiotensin-converting enzyme inhibitor

ARB = angiotensin receptor blocker

BB = beta blocker

GDMT = guideline-directed medical therapy

HF = heart failure

LVEF = left ventricular ejection fraction

PA = pulmonary artery

Higher cardiac filling pressures in patients with heart failure (HF) are associated with higher risk for hospitalizations and mortality (1,2). Regardless of left ventricular ejection fraction (LVEF), filling pressures rise more than 2 weeks before rehospitalization (3). In the COMPASS-HF (Chronicle Offers Management to Patients with Advanced Signs and Symptoms of Heart Failure) study, active adjustment in medications in response to elevated filling pressures transmitted by an implanted device decreased hospitalizations more effectively than therapy guided only by clinical signs and symptoms of congestion (4). In patients with an estimated baseline pulmonary artery (PA) diastolic pressure higher than 25 mm Hg the risk of HF events decreased by 50% if the pressure was subsequently lowered below 25 mm Hg (5). However, COMPASS-HF (6) lacked definitions for target "optivolemia" filling pressures and therapy algorithms. As a result, high filling pressures at baseline generally remained high throughout the study, during which the average estimated PA diastolic pressure was 28 ± 7 mm Hg (5). Ambulatory monitoring of intracardiac pressures is only useful if it can be translated into effective interventions.

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HF management guided by monitoring of PA pressure was refined in the CHAMPION trial (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in Class III Heart Failure) to include guidelines on how to treat elevated PA pressures to achieve protocol-defined target filling pressure ranges with titration of diuretics and vasodilators (7). This study compared HF hospitalization rates in patients whose therapy was guided by PA pressures (active monitoring group) with patients whose uploaded PA pressures were not available to the clinicians. In this "blind therapy group," investigators adjusted therapy according to usual clinical information. In CHAMPION, PA pressure-guided HF management was associated with a 28% reduction in HF hospitalization rates after 6 months and 37% after an average follow-up of 15 months relative to management guided by clinical assessment alone (8).

We analyzed the frequency and rationale for medication changes in relationship to PA pressure data obtained during the CHAMPION trial to determine what interventions were linked to decreased hospitalizations during ambulatory PA pressure-guided management, and what baseline PA pressure and therapies delivered were associated with benefit.

METHODS

STUDY DESIGN. The study design and main results of the CHAMPION trial have been previously published in detail (7,8). Briefly, from 64 U.S. study sites the trial enrolled 550 New York Heart Association functional class III patients who had been hospitalized for HF in the previous year. Patients were enrolled regardless of LVEF or HF etiology and were required to already be taking all appropriate guideline-directed medical and device therapies (GDMT) (9). The CHAMPION trial was a randomized, controlled, single-blind study with all patients undergoing right heart catheterization and implantation of the wireless hemodynamic monitoring system (CardioMEMS HF System, St. Jude Medical, Inc., Atlanta, Georgia) (10–12). For all patients, physicians had access to baseline hemodynamic information from the right heart catheterization. After device implantation, patients were randomized 1:1 to the active monitoring group or to the blind therapy group. All patients in both groups were instructed to transmit daily PA pressure readings from home. Real-time PA pressure information from home monitoring was available to physicians only for patients randomized to the active monitoring group. The primary endpoint for the CHAMPION trial was HF hospitalization rates, which were evaluated at 6 months of follow-up. All hospitalizations and deaths were adjudicated by a clinical events committee blinded to study group assignment.

Protocol recommendations for PA pressure-guided HF management. Patients in both arms were treated according to clinical symptoms and signs of excessive volume, including daily weight measurements. The central hypothesis was that medication adjustment guided by PA pressure would reduce HF hospitalizations compared with reliance solely on clinical symptoms and signs. CHAMPION trial investigators were given specific recommendations on

consulted for St. Jude Medical, Medtronic, and Biotronik. Dr. Bourge has received grant support and consulting honoraria from CarioMEMS and St. Jude Medical. Mr. Bauman is employed by St. Jude Medical in Global Research and Development. Dr. Abraham has received consulting fees from CardioMEMS/St. Jude Medical for roles as Co-Principal Investigator for the CHAMPION trial and Principal Investigator for the LAPTOP-HF trial; and has received speaker honoraria and travel fees from St. Jude Medical.

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