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Limitations of right heart catheterization in the diagnosis and risk stratification of patients with pulmonary hypertension related to left heart disease: Insights from a wireless pulmonary artery pressure monitoring system

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BACKGROUND: Although right heart catheterization (RHC) remains the gold standard for assessment of hemodynamics in patients with known or suspected pulmonary hypertension (PH), there are significant limitations to this type of assessment. The current study evaluates the limitations of RHC in the diagnosis of left heart–related PH (World Health Organization group II) among patients enrolled in the CHAMPION trial and discusses insights into patient risk from home implantable hemodynamic monitor (IHM) data that were not identified at the time of the RHC procedure.

METHODS: The CHAMPION trial enrolled 550 New York Heart Association functional class III patients who had been hospitalized for heart failure (HF) in the previous year, regardless of left ventricular ejection fraction or etiology. Hemodynamic data obtained during baseline RHC were compared with IHM data obtained during the first week of home readings. HF hospitalization rates and mortality were analyzed to assess patient risk.

RESULTS: The study population for this retrospective analysis comprised 537 patients with available IHM data. For 320 patients in the PH_{RHC} group, home IHM data confirmed the RHC findings with similar mean pulmonary artery pressures obtained from both methods (36 mm Hg vs 36 mm Hg, $p = 0.5066$). However, of the 217 patients in the No PH_{RHC} group, 106 patients (48.8%) exhibited PH based on the home IHM data (PH_{IHM} group). The remaining 111 patients (51.2%) in the No PH_{RHC} group had no evidence of PH on the IHM data (No PH_{IHM} group). Patients in the No PH_{RHC}/PH_{IHM} group had significantly higher mean PA pressures on IHM than patients in the No PH_{RHC}/No PH_{IHM} group (31 mm Hg vs 18 mm Hg, $p < 0.0001$). Patients in the No PH_{RHC}/No PH_{IHM} group had significantly lower HF hospitalization rates than patients in the No PH_{RHC}/PH_{IHM} group (0.25 vs 0.49, incidence rate ratio = 0.51, 95% confidence interval = 0.33–0.77, $p = 0.0007$).

CONCLUSIONS: Using only RHC, World Health Organization group II PH may be significantly underdiagnosed. In patients with left-sided HF and resting mean PA pressure ≤25 mm Hg during RHC, more

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frequent PA pressure monitoring using an IHM device can provide additional data for improved diagnosis and patient risk stratification compared with a single RHC alone.
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Right heart catheterization (RHC) is an essential procedure in the diagnostic evaluation of patients with pulmonary hypertension (PH).[1,2] Hemodynamic data obtained by invasive RHC can help to determine the etiology of PH and can provide prognostic information to assist in individual patient risk stratification. RHC remains the gold standard for assessment of hemodynamics in patients with known or suspected PH; however, there are significant limitations to this type of assessment.[1,3] In the catheterization laboratory, hemodynamic variables are typically measured at rest with patients in the supine position, and these values may underestimate the presence and severity of PH and may not accurately reflect the true extent of hemodynamic compromise.

In addition, exaggerated variability in hemodynamic waveforms secondary to ventilation and improper leveling of the pressure transducer can lead to errors in hemodynamic interpretation and mischaracterization of the etiology of PH in some patients.[4] At the Fifth World Symposium on Pulmonary Hypertension, significant attention was given to the role of RHC in the evaluation of PH, and the World Symposium on Pulmonary Hypertension working group outlined specific recommendations to ensure best practices for performance and interpretation of the RHC procedure to try to mitigate some of these potential sources of error.[3]

Nonetheless, these recommendations do not address a more critical limitation of RHC, which is the fact that RHC can provide only a "snapshot" of a patient's hemodynamic profile at a single time point, often in an artificial hospital-based environment, which may not reflect hemodynamic conditions in the home environment. This particular limitation is inherent to the technology of RHC, and it is not presently feasible to perform serial RHC measurements in outpatients on a daily basis. In addition, it is currently impossible to obtain RHC measurements remotely from a patient's home, and insight into the hemodynamic conditions under which patients spend most of their time remains limited.

Newer technologies, such as implantable hemodynamic monitors (IHMs), can address some of these limitations of RHC and can provide greater insights into the hemodynamic profile of patients with PH by enabling frequent, accurate assessment of hemodynamic information from home. The CHAMPION trial was a prospective, multicenter, randomized, single-blind clinical trial in patients with New York Heart Association functional class III heart failure (HF) symptoms regardless of left ventricular ejection fraction or etiology in which all patients were implanted with an IHM (St. Jude Medical, Inc., Atlanta, GA) and transmitted daily PA pressure readings from home.

The results of the CHAMPION trial confirmed that a HF management strategy incorporating data from the IHM system was superior to standard of care methods and allowed for further optimization of patient medical management leading to fewer hospitalizations for HF. This strategy also resulted in significant decreases in PA pressures in the treatment group, fewer patients hospitalized for HF, more days alive outside of the hospital, and improved quality of life. The present study evaluates the limitations of RHC in the diagnosis of left heart–related PH (WHO group II) among patients enrolled in the CHAMPION trial and discusses insights into patient risk from the home IHM data that were not identified at the time of the RHC procedure.

Methods

Patients

The CHAMPION trial enrolled 550 New York Heart Association functional class III patients who had been hospitalized for HF in the previous year at 64 heart centers in the United States and has been described in detail elsewhere.[5,6] Briefly, patients were enrolled regardless of left ventricular ejection fraction or etiology and received all appropriate drug and device treatments for HF at optimal or best-tolerated stable doses before enrollment, according to American College of Cardiology/American Heart Association guidelines.[7] All patients underwent baseline invasive hemodynamic evaluation in conjunction with RHC and were implanted with the PA pressure sensor using a transvenous catheter delivery system. Major exclusion criteria included a history of recurrent pulmonary embolism or deep venous thrombosis, cardiac resynchronization therapy device implantation within the preceding 3 months, and stage IV or V chronic kidney disease (glomerular filtration rate <25 ml/min). The study complied with the Declaration of Helsinki, the institutional review board of each participating center approved the study protocol, and all patients provided written informed consent.

Study design

After RHC hemodynamic evaluation and PA pressure sensor implantation, patients were randomly assigned 1:1 to either the treatment group, where physicians had access to PA pressure information from the IHM, or the control group, where physicians were blinded to this information. All patients in both groups transmitted daily PA pressure readings from home immediately after discharge. Patients were instructed to take readings at the same or similar time each day to provide consistency across home readings. The PA pressures were typically obtained in the morning and in the resting, supine state by means of laying down on a padded pillow encasing the antenna of the home electronic control module. There was no specific instruction with regard to transmitting readings relative to recent physical activity. With each download, 18 seconds of PA pressure data were transmitted, and patients were asked to transmit PA pressure daily. With the availability of patient hemodynamic information from RHC and home IHM data, the CHAMPION trial provided a unique opportunity to evaluate potential differences between these patient hemodynamic environments and whether or not they are associated with differences in clinical