Device that detects congestion in the lung improves heart failure outcomes

April 4 2016

In patients with heart failure, use of an investigational device that monitors the accumulation of fluid in the lungs appeared to cut heart failure-related hospitalizations by more than half, meeting the study's primary endpoint, and reduced deaths from any cause by 39 percent per year compared with standard assessment and treatment, researchers reported at the American College of Cardiology's 65th Annual Scientific Session.

The Edema Guard Monitor alerts patients to an increase in fluid in the lungs, also called pulmonary congestion or edema, before they have symptoms, said Michael K. Shochat, M.D., of Hillel Yaffe Heart Institute in Hadera, Israel, and lead author of the study. Shochat is also president of RS Medical Monitoring, the Israel-based company that manufactures the Edema Guard Monitor.

"By the time a patient shows clinical signs of pulmonary congestion, the condition is already at an advanced stage," Shochat said. "Many patients need emergency hospitalization and have a high probability of sustaining irreversible damage to the heart and lungs. In this study, patients who used the Edema Guard Monitor started taking medication well before pulmonary congestion reached an advanced stage."

The Edema Guard Monitor—a stand-alone device—measures lung impedance, or resistance to electrical current, Shochat said. Healthy, air-filled lungs are highly resistant to electrical current, whereas lungs swollen by fluid are less resistant. In pulmonary congestion, the lungs

gradually become more and more swollen by fluid. Existing techniques for monitoring worsening pulmonary congestion, such as periodic chest X-rays or computed tomography (CT) scans of the lungs, are costly or not highly effective. Preliminary studies had suggested that lung impedance-guided treatment could reduce hospitalizations for heart failure.

"This study shows for the first time that a noninvasive lung impedance monitor can be used to detect pulmonary congestion in its earliest stages and that adequate medical treatment at that early stage can significantly reduce both hospitalizations and mortality," Shochat said.

The IMPEDANCE-HF trial was conducted at two medical centers in Israel and included 256 patients with chronic heart failure whose hearts were pumping blood at less than half of the normal rate. Patients were 67 years of age on average, and 80 percent were male. Before patients were randomized, they received three months of treatment through outpatient clinics to achieve maximal doses of guideline-directed medications to manage congestive heart failure. All patients attended monthly outpatient visits during which a technician measured their lung congestion using the Edema Guard Monitor and their physician performed a standard clinical assessment.

Patients were randomly assigned to one of two groups. In the treatment group, medication was prescribed or adjusted at each visit based on the results of clinical assessment and lung congestion measurement with the Edema Guard Monitor. In the control group, medication was prescribed or adjusted based on clinical signs of lung congestion. The primary endpoint was hospitalizations due to heart failure. Secondary endpoints were hospitalizations and deaths from any cause. The average follow-up time was 48 months in the treatment group and 39 months in the control group.

In the treatment group compared with the control group, hospitalizations due to heart failure decreased by 58 percent during the first year of treatment, and the frequency of heart failure-related hospitalization decreased by 56 percent per year during the entire follow-up period, meeting the study's primary endpoint. For the entire follow-up period, deaths from heart failure were reduced by 62 percent per year and deaths from any cause decreased by 39 percent per year in the treatment group compared with the control group.

The hope is that patients will eventually be able to use the device at home to measure their lung impedance once or twice a day, Shochat said.

A limitation of the study is that it excluded patients with less severe heart failure, or those whose hearts were pumping blood at more than half of the normal rate, and that the results cannot be extended to that group of patients, Shochat said. Results from an ongoing randomized trial of the Edema Guard Monitor in patients with less severe heart failure are expected in 2019.

More information: Michael Kleiner Shochat et al. Non-Invasive Lung IMPEDANCE-Guided Preemptive Treatment in Chronic Heart Failure Patients: a Randomized Controlled Trial (IMPEDANCE-HF Trial)., *Journal of Cardiac Failure* (2016). DOI: 10.1016/j.cardfail.2016.03.015

Provided by American College of Cardiology