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Study supports biomarker assay for ER heart failure diagnosis

A multicentre study supports the value of a biomarker to accurately diagnose or rule out acute heart failure in patients seen for shortness of breath at hospital emergency departments. Its findings, published in the Journal of the American College of Cardiology, also validate the use of age-adjusted thresholds of the protein NT-proBNP to diagnose heart failure in a wide range of such patients.

NT-proBNP (N-terminal pro-brain natriuretic peptide) and a related protein called BNP (B-type natriuretic peptide) are both produced when the cardiac muscle is under stress. Previous studies of the value of NT-proBNP testing suggested age-based diagnostic cutoffs for identification of acute heart failure: 450 pg/ml for patients under 50, 900 pg/ml for those 50 to 75, and 1,800 pg/ml for those over 75. An NT-proBNP level of 300 or below appeared to rule out acute heart failure no matter the patient's age.

While use of those cutoffs has been incorporated into diagnostic guidelines internationally, the only NT-proBNP diagnostic cutoffs approved by the U.S. Food and Drug Administration (FDA) are 125 pg/ml for patients under 75 and 450 pg/ml for those 75 and older – levels designed for use in conjunction with outpatient treatment.

The current study, conducted by the Baim Institute for Clinical Research, sought to determine whether the NT-proBNP test remains useful for assessment of the current population of patients with heart failure.

Over the past 15 years, "the characteristics of patients with heart failure have changed – they tend to be older, are more likely to be women and to have additional complications – making a contemporary reassessment of the assay's performance necessary," explains James Januzzi Jr., MD, of the Massachusetts General Hospital Division of Cardiology, who led the study.

Conducted in 2015 and 2016 at 19 sites in the U.S. and Canada, the study enrolled 1,461 adult patients who had come to hospital emergency departments with shortness of breath or other breathing difficulties. Blood samples to be measured for NT-proBNP levels were taken upon study enrolment, and determination of the presence of acute heart failure – separate from the clinical diagnosis that guided participants' care – was made by clinicians blinded to individual participants' NT-proBNP levels. Overall, 277 patients – 19 percent of total study enrolment – were determined to have acute heart failure.

Comparison of participants' NT-proBNP levels with their eventual diagnoses supported the usefulness of the age-based cutoff levels and that a level below 300 strongly excluded a heart failure diagnosis.

These results were consistent across all groups of participants, no matter their age, gender, racial or ethnic background or the presence of conditions like obesity or kidney disease.

"Given the changes in the types of patients with heart failure we see today, it's quite remarkable how reliable this test is," notes Januzzi, who is the Hutter Family Professor of Medicine in the Field of Cardiology at Harvard Medical School. Januzzi and his colleagues anticipate FDA approval of the age-based NT-proBNP cutoffs for emergency department diagnosis.

Source: Massachusetts General Hospital
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