心臓再同期療法は軽度心不全患者において有用である（Abstract＃21768）

RAFT：軽度－中等度の症状を有する心不全患者において心臓再同期療法を追加することにより死亡および心不全による入院が減少する

RAFT: Adding cardiac-resynchronization therapy reduces deaths, heart failure hospitalizations in patients with mild-to-moderate symptoms

薬物療法および埋め込み型除細動器で治療されている軽度－中等度の症状を有する心不全患者に心臓再同期療法（ICD）を追加することにより死亡および心不全による入院が有意に減少する、とのレイトブレイキング臨床試験の結果が2010年AHA学会で発表され、New England Journal of Medicineオンライン版に掲載された。外来心不全患者に対する再同期/除細動トライアル（Resynchronization/defibrillation for Ambulatory heart-Failure Trial：RAFT）において研究者らは、軽度から中等度の心不全および左室機能低下を有する患者1,798人（平均年齢66歳、男性82%）をICDまたはCRT機能も備えたICDを受ける群に無作為に割り付けた。両群ともに薬物療法も受けた。平均追跡期間は40ヵ月であり、この種のスタディでは最長のスタディの1つであった。統計学的に有意な結果として、ICD/CRT併用群はCRTを受けない群と比較し死亡または心不全による入院率が25%低いことが示された。ICD/CRT併用群患者はまたCRTを受けない患者と比較し総死亡率も25%低かった。これらの結果から、ICD/CRTは軽度から中等度の心不全患者において価値のある治療であることが示されたと研究者らは述べている。

Full Text

Adding cardiac-resynchronization therapy (CRT) significantly reduces deaths and heart failure hospitalizations among heart failure patients with mild-to-moderate symptoms being treated with medication and an implantable cardioverter defibrillator (ICD), according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2010.

In the Resynchronization/defibrillation for Ambulatory heart-Failure Trial (RAFT), investigators randomized patients with mild to moderate heart failure to receive either an ICD or an ICD equipped to provide cardiac-resynchronization therapy (CRT). With CRT, special leads from the ICD pace the heart's main chambers to beat in synchronization. Both groups also received standard medical treatment.

Previous studies have shown that resynchronization therapy combined with ICD treatment can reduce symptoms and hospitalizations among patients with severe heart failure. Before results of RAFT, the therapy's effects on patients with milder symptoms and on death rates weren't clear.

In a statistically significant finding, patients on the combined ICD/CRT regimen were 25 percent less likely to die or be hospitalized for heart failure, compared to patients who didn't receive CRT. Patients on the combined ICD/CRT treatment were also 25 percent less likely to die of any cause, compared to patients who didn't receive CRT.

"This study conclusively demonstrated that this particular therapy, in addition to an ICD, will save lives," said Anthony Tang, M.D., the study's lead author and an electrophysiologist at Royal Jubilee Hospital in Victoria, B.C., Canada. "For patients, and for the physicians who treat them, this definitely showed that we can reduce hospitalization, suffering and dying."

Although complications were minimal among all participants, the wires connecting the device to the heart were more likely to become dislodged among ICD/CRT patients than among those with ICD alone (6.9 versus 2.2 percent and a statistically significant difference).

Investigators enrolled 1,798 patients with mild to moderate heart failure and left ventricular dysfunction in a prospective study at 34 sites in Canada, Europe, Australia and Turkey between January 2003 and February 2009. The patients' average age was 66 years, and 82 percent were male. Two-thirds of participants had heart failure related coronary artery disease, and one-third had heart failure of undetermined origin.

Researchers compared death rates and heart failure hospitalizations lasting longer than 24 hours between the ICD-only group and the ICD/CRT group. Average follow-up was 40 months, one of the longest for a study of this kind.

"CRT alone, without a defibrillator, has been demonstrated to save lives," said Tang, who is CIHR Research Chair and professor of medicine at the University of British Columbia and adjunct professor of medicine at the University of Ottawa. "The defibrillator also has been shown to save lives. The big question is, when the two are added together does it still make sense?"

To further resolve the issue, the investigators are analyzing the cost-effectiveness of ICD/CRT compared with ICD only and quality-of-life data from the study.

Co-authors are George A. Wells, Ph.D.; Mario Talajic, M.D.; J. Malcolm O. Arnold, M.D.; Robert Sheldon, M.D.; Stefan H. Hohnloser, M.D.; Stuart Connolly, M.D.; Graham Nichol, M.D.; Jean L. Rouleau, M.D.; David H. Birnie, M.D.; Raymond Yee, M.D.; and John Sapp, M.D. Author disclosures are on the abstract.

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