再同期療法により軽症の無症状患者の心不全リスクが軽減する

MADIT-CRT：再同期療法により軽症の無症状患者の心不全リスクが軽減する

MADIT-CRT: Resynchronization therapy reduces risk of heart failure in asymptomatic patients with mild disease

無症状または軽症状を有する心不全患者を、除細動器付き植込み型心臓再同期装置（CRT-D）に無作為に割り付けられた患者は、標準的な植込み型除細動器（ICD単独）に割り付けられた患者と比較し、心不全または死亡のリスクが34%低い（HR 0.66；p=0.001）との多施設心臓再同期療法付き自動除細動器植込みトライアル（MADIT-CRT：Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy）の結果がESC 2009で発表された。このトライアルではNew York心機能クラスIまたはIIの左室機能低下（左室駆出率<30%）を伴いQRS幅>130msの虚血性または非虚血性心疾患患者を対象とした。トライアルは、心臓再同期療法に優位性が認められた（p=0.001）ため4.5年間で終了し、その間に1,820人の患者が組み入られた。患者はCRT-DまたはICD単独を受ける群に3：2の割合で無作為に割り付けられ、全ての患者がトライアルの期間を通じて最大限の心不全薬物療法を受けた。男性および女性、若年患者および高齢患者、心機能不全の軽症患者およびそれよりも重症の患者、虚血性および非虚血性全ての患者サブグループにおいてCRT-D療法の優位性が認められた。

Full Text

Asymptomatic or mildly symptomatic cardiac patients randomized to an implanted cardiac resynchronization device with defibrillator (CRT-D) have a 34% lower risk of heart failure or death than those receiving a standard implanted cardioverter defibrillator (ICD-only) (HR 0.66, p=0.001), according to results from the MADIT-CRT (Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy) study.

The MADIT-CRT study was a randomized trial designed to determine if CRT-D therapy would reduce the primary endpoint (all-cause mortality or heart failure events, whichever occurred first) when compared to patients receiving ICD-only therapy. The study population involved cardiac patients in New York Heart Functional Class I or II (no or mild symptoms) who had either ischemic or non-ischemic heart disease with left ventricular dysfunction (ejection fraction <30%) and QRS duration of >130ms on ECG.

Cardiac resynchronization therapy (CRT) with or without a defibrillator is indicated for use in patients with severe heart failure (New York Heart Association Class III/IV), and CRT has been shown to reduce symptoms, mortality and hospitalization in very sick cardiac patients. The question that remained was whether CRT would improve heart function and slow or prevent the development of heart failure in the less severe NYHA class I/II cardiac patients (moderately high risk, but with no or mild symptoms) by intervening early in the course of the disease before the development of advanced symptoms.

The MADIT-CRT trial enrolled and followed 1820 patients from 110 centers in Europe, Canada, and the USA during a 4.5-year period between December 2004 and 22 June 2009, when the trial was officially ended because of the superiority of the cardiac resynchronization therapy (p=0.001). Patients were randomized in a 3:2 fashion to receive either CRT-D or ICD alone, and all patients received optimal medical therapy for heart failure during the trial.

The superiority of CRT-D therapy was found to be present in all patient sub-groups, including those with ischemic and non-ischemic types of heart disease, as well as in males and females, younger and older patients, and those with mild and more advanced heart dysfunction.

Commenting on the results, the study's principal investigator, Professor Arthur J Moss from the University of Rochester Medical Center, New York, USA, said: "Cardiac resynchronization therapy was dramatically effective in this large study population, with a 34% reduction in the risk of all-cause mortality or heart failure. The benefit is dominated by a 41% reduction in heart failure events. These results validate a new indication for cardiac resynchronization therapy in the prevention of heart failure in at-risk asymptomatic or mildly symptomatic cardiac patients. It seems likely that this preventive CRT-D therapy will have widespread application and utilization."

Conference News