CRTは臨床転帰を改善する

REVERSE：両心室ペーシングを最大限の薬物療法に組み合わせることで軽度心不全患者に有益性がもたらされる

REVERSE: Biventricular pacing combined with optimal medical therapy is beneficial in patients with mild heart failure

心臓再同期療法（CRT）を評価した24ヵ月間のヨーロッパのスタディの結果、心臓の同期不全を有する軽度心不全患者に対し最大限の薬物療法に両心室ペースメーカーを組み合わせることにより、最大限の薬物療法のみを受けたコントロール群と比較し悪化の程度が有意に低下したことが示されたとの研究結果が2009年第58回American College of Cardiology学会で発表された。このスタディは、薬物療法で良好に治療されているが軽度の症状のある患者または過去に心不全を有したwide QRSの無症状の患者に対してCRTの有効性を評価した、左室収縮不全患者における再同期リバースリモデリング（REVERSE）の多国籍コホートスタディである。CRTと最大限の薬物療法の併用（CRT ON）と最大限の薬物療法のみ（CRT OFF）の群における悪化のパーセンテージを比較した一次エンドポイントは経過とともに増加し、疾患の進行は停止しないことが示された。しかし、悪化の程度はCRT OFF群と比較するとCRT ON群において有意に低かった。CRT ON群において、左室機能の改善は著明でありその程度は18ヵ月の間に向上し効果はスタディの最後の6ヵ月間持続した。一方、CRT OFF群では観察期間終了に向かい悪化した。

Full Text

A 24-month European study measuring cardiac resynchronization therapy (CRT) showed that using a biventricular pacemaker combined with drug therapy on patients with mild heart failure and ventricular dyssynchrony showed the magnitude of worsening at measured time points was significantly lower than in the control group who received optimal medical therapy alone, according to research presented at the American College of Cardiology's 58th annual scientific session.

Worsening is defined as either the occurrence of heart failure hospitalizations, death, the need to be programmed to the opposite randomization assignment, worse New York Heart Association (NYHA) functional class or worse wellbeing as judged by the patient.

This study is a multi-national European cohort of the REVERSE trial presented at ACC08 which was a one-year multi-center trial that gauged whether CRT plus optimal medical therapy (CRT ON) can manage the progression of heart failure compared to optimal medical therapy alone (CRT OFF). The results from that earlier one-year study, which included both United States and European patients, failed to show that adding CRT to optimal medical therapy significantly influenced the primary end point, which was percent worsening. However, the data did show that device therapy most likely improved left ventricular function and prevented heart-failure hospitalizations - both secondary endpoints of the study.

"We wanted to assess if CRT in medically well-treated but mildly symptomatic patients or in asymptomatic patients with previous heart failure and with a wide QRS could modify disease progression," said Cecilia Linde, M.D., Ph.D, Karolinska University Hospital, Stockholm, Sweden.

The primary endpoint of comparing the worsening percentage in both CRT ON and CRT OFF increased over time, indicating disease progression did not stop. However, the magnitude of worsening at each time point was significantly lower in the CRT ON when compared to the CRT OFF group.

Improvement in left ventricular function was marked and progressed over 18 months with sustained benefit over the last six months of the study period. In contrast, the disease progression, being worsening ventricular function, in the CRT OFF group was seen towards the end of the observation period.

"We noticed that the 262 European patients improved by CRT, regarding the clinical composite response and in terms of sustained reverse remodeling," Linde said. "This translates into a significant decrease in death and heart failure hospitalizations."

As with the main REVERSE trial, there was no significant benefit in the NYHA functional classification, quality of life or exercise capacity, which is not surprising in mildly symptomatic or asymptomatic patients.

"Optimal heart failure medication, when properly introduced, means that patients who are admitted for heart failure for the first time may revert to an asymptomatic or mildly symptomatic stage," Linde said.

Left ventricular function does not normalize or improve sufficiently by administering drugs in all patients. In these patients, disease progression that results in worsening symptoms or even the need for hospitalization due to heart failure over the following 12 to 24 months is expected.

"Our study demonstrated that CRT in a subset of such patients with wide QRS easily detected with an ordinary ECG and indicating delayed ventricular activation, is an important addition to treatment that achieves substantial reverse modeling, which postpones the time to the next heart failure progression," Linde said.

"Thus, we believe it impacts disease progression."

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