電気刺激は心不全の予後を改善する

FIX-HF-5：新たなデバイスは心臓のポンプ機能を強化し運動耐容能およびQOLを改善する

FIX-HF-5: Novel device helps heart to pump more forcefully improving exercise capability and quality of life

電気刺激を心臓に送り毎回の収縮力を強化する治験デバイスは心不全患者の治療に有望であることが示された、と2009年第58回American College of Cardiology学会で発表された。FIX-HF-5スタディでは、駆出率35%以下で心電図上QRSの狭いNYHAクラスIIIまたはIVの心不全患者を、最大限の薬物療法単独（213人）または心収縮力調整（CCM）と最大限の薬物療法を組み合わせた群（215人）に無作為に割り付けた。6ヵ月後の時点で安全性は両群ともに等しく良好であったが、Peak VO2およびQOL（スコアが低いほどQOLが高い）はCCM群の方が良好であった(pVO2は0.65mL/kg/min改善し[p=0.024]，QOLスコアは9.7ポイント低下した[p<0.0001])。無酸素性代謝閾値に有意差はなかった。しかし、中等度の心不全（NYHAクラスIII）で駆出率が25%以上の患者185人のみを解析したところ、三つの指標は全てCCM群において有意に改善していた（無酸素性代謝閾値は0.64mL/kg/min多く[p=0.03]，pVO2は1.31mL/kg/min多く[p=0.001]，QOLスコアは10.8ポイント低かった[p=0.003]）。

Full Text

An investigational device that delivers electrical impulses to the heart, thereby strengthening the force of each contraction, is showing promise in patients with heart failure, helping them to exercise more vigorously and promoting a greater sense of well-being, according to research presented today at the American College of Cardiology's 58th annual scientific session.

The FIX-HF-5 study found that cardiac contractility modulation (CCM) significantly improved peak ventilatory oxygen uptake (pVO2) and quality of life in patients with moderate-to-severe heart failure, when compared to the best available medical care. In patients with only moderate heart failure, CCM also improved anaerobic threshold, a new marker being tested as a gauge of treatment effectiveness.

"Cardiac contractility modulation shows great promise for the treatment of heart failure," said William T. Abraham, M.D., a professor of medicine, physiology, and cell biology and director of cardiovascular medicine at The Ohio State University in Columbus. "It has the potential to be a real breakthrough."

The CCM device - known as the Optimizer (Impulse Dynamics, Orangeburg, NY) - looks much like a pacemaker and, like that device, is implanted under the skin in the chest with wires threaded into the right side of the heart. Unlike a pacemaker, which controls the heart rate and rhythm, CCM delivers its electrical impulses precisely when the heart is recharging between beats and will not respond by contracting. Instead, the heart converts the electrical energy into a more forceful contraction the next time it beats.

For the study, researchers recruited 428 patients with NYHA class III or IV heart failure, an ejection fraction of ≤35 percent, and narrow QRS tracings on the electrocardiogram (which would rule out cardiac resynchronization).

Patients were randomly assigned to optimal medical therapy alone (213 patients) or CCM plus optimal medical therapy (215 patients). At baseline and six months after device implantation, researchers tested the effectiveness of CCM by having all patients exercise on a treadmill while wearing a mask that measures the air that is breathed in and out. The investigators evaluated both peak VO2, an indicator of maximum exercise capacity, and a new indicator, anaerobic threshold, which shows how vigorously a patient can exercise before running out of ready energy reserves and switching to a less efficient form of metabolism. Researchers also measured quality of life using the Minnesota Living with Heart Failure Questionnaire. With this questionnaire, a lower score indicates a better quality of life.

At six months, safety was equally good in both groups, while Peak VO2 and quality of life were significantly better among patients treated with CCM, as compared to optimal medical therapy alone. Peak VO2 was better by 0.65 mL/kg/min, p = 0.024; and the quality of life score was 9.7 points lower, p<0.0001. There was no significant difference in anaerobic threshold.

However, when researchers analyzed data only for the 185 patients with moderate heart failure (NYHA class III) and an ejection fraction ≥25 percent, all three indicators improved significantly more in the CCM group (anaerobic threshold was better by 0.64 mL/kg/min, p = 0.03; pVO2 was better by 1.31 mL/kg/min, p = 0.001; and the quality of life score was lower by 10.8 points, p = 0.003).

"It may be that some people are too sick, or their heart is too damaged, to respond to CCM," Abraham said. "This study has provided us with important insight into the 'sweet spot,' where this therapy is most effective."

ACC2009特集