患者やドナーからの幹細胞は病的心の治療に役立つ可能性がある（LBCT-19942）

POISEIDON:同種幹細胞は心筋症によるLV機能低下患者において安全である

POISEIDON: Allogeneic stem cells are safe in for patients with LV dysfunction due to cardiomyopathy

心筋症によるLV機能不全患者の治療に幹細胞を患者またはドナーいずれから得ても安全に治療でき有効性は同等であるとのLate-Breaking Clinical Trialの結果が2012年American Heart Association学会で発表され*Journal of the American Medical Association*に掲載された。The Comparison of Allogeneic vs. Autologous Bone Marrow Derived Mesenchymal Stem Cells Delivered by Transendocardial Injection in Patients with Ischemic Cardiomyopathy trial（POISEIDON）は、同種と自家間葉幹細胞（MSCs）を比較し13か月間追跡した第Ⅰ/Ⅱ相無作為化比較試験である。慢性虚血性心筋症患者30人が様々な用量のMSCsを投与された。半分は自己細胞を投与され、残りの半分はドナー細胞を投与された。心不全クラスはドナー細胞を投与された患者の28%において改善し、自己細胞を投与された患者の50%において改善した。過去の心筋梗塞による梗塞サイズは両群ともに平均30%減少し、一部の患者ではQOLが向上した。同種 MSCsがドナー特異的同種免疫反応を有意に刺激することはなかった。MSCsを用いた新たな心筋再生のためには大量の幹細胞を培養する必要があり、それには6～8週を要する。既に準備されたドナー細胞を使用すれば、この治療の遅延は回避できる可能性がある。

Full Text

Stem cells taken from patients or donors can treat people with LV dysfunction due to cardiomyopathy safely and with similar effectiveness, according to late-breaking clinical trial results presented at the American Heart Association's Scientific Sessions 2012 and published in the *Journal of the American Medical Association*.

The Comparison of Allogeneic vs. Autologous Bone Marrow Derived Mesenchymal Stem Cells Delivered by Transendocardial Injection in Patients with Ischemic Cardiomyopathy trial (POISEIDON) is a phase Ⅰ/Ⅱ randomized comparison of allogeneic and autologous mesenchymal stem cells (MSCs) with 13-month follow-up.

"This cell therapy clearly had some clinical benefits and the mesenchymal stem cells from donors were just as safe as those from the recipient," said Joshua Hare, M.D., the lead study author. "Even in patients who had heart attacks several decades before treatment, both donor and recipient stem cells reduced the amount of scarring substantially, by one-third."

The MSCs — unique because the body's protective antibodies don't attack them — are found in adults' bone marrow.

Previous studies indicated that MSCs might improve heart muscle function in patients with heart scarring from a prior heart attack.

The 13-month trial is the first to compare the safety and efficacy of MSCs taken from the patients themselves against MSCs provided by donors. Thirty patients with chronic ischemic cardiomyopathy received various doses of MSCs. Half received their own cells, while the other half received donor cells. Heart failure class improved in 28 percent of those receiving donor cells, and in 50 percent of those receiving their own cells. Infarct size from past myocardial infarction was reduced by about 30 percent on average in both groups, and some patients had improved quality of life. Allogeneic MSCs did not stimulate significant donor-specific alloimmune reactions.

Regenerating new heart muscle with MSCs requires growing large amounts of the stem cells, which takes six to eight weeks. Using already-prepared donor cells might avoid this delay to treatment.

"Because antibodies don't attack MSCs, donor cells can be prepared in advance and stored until needed," said Hare, a professor of medicine and director of the Interdisciplinary Stem Cell Institute at the University of Miami Miller School of Medicine in Florida. "Perhaps using donor cells is the more feasible approach."

The stem cells were delivered directly into the damaged area of patients' heart muscle using a catheter with a needle tip. "An additional important finding was the safety of this new cardiac catheterization technique," said study co-author Alan Heldman, M.D., a cardiologist and Professor of Medicine in the University of Miami Health System, who performed the minimally-invasive procedures.

Hare, Heldman and colleagues are planning a larger, placebo-controlled trial — necessary before MSCs can become a standard therapy for ischemic cardiomyopathy and congestive heart failure.
Co-authors names are on the abstract.

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