小型のLVAD代替療法

部分的循環補助により薬物療法の無効な心不全患者の心機能が改善する

Partial circulatory support improves heart function in medically refractory heart failure patients

AAバッテリサイズで重さ25gのポンプにより薬物療法の無効な心不全患者の部分的な循環が補助され血行動態および心機能が改善した、と2009年第58回American College of Cardiology学会で発表された。このスタディでは、たった2.5～3.0L／分の血液を拍出するだけで心機能を補助する循環補助装置を16人の患者（男性13人、平均年齢52歳、ベースラインの平均駆出率20%）に植え込んだ。植え込み前の平均動脈圧は71mmHg、平均肺毛細管楔入圧は29mmHg、心拍出係数は1.9L/min/m^2であった。16人中13人の患者（81%）が3ヵ月後も生存していた。そのうち7人に10.6±6週の時点で右心カテーテルを施行した。平均動脈圧（70±6mmHg対80±10mmHg、P=0.04）および心拍出係数（2.1±0.4対2.9±0.6、P=0.02）の増加と肺毛細管楔入圧の大幅な低下（30±5対16±4、P=0.002）が認められた。peak VO2は3.0±0.5ml/kg/min増加した（10.7±2.2対13.7±2.2、P= 0.008）。

Full Text

A pump the size of an AA battery weighing 25 grams provided partial circulatory support and improved hemodynamics and cardiac function when implanted in patients with medically refractory heart failure, according to research presented at the American College of Cardiology's 58th annual scientific session.

The Synergy™ Pocket Micro-pump may expand the use of circulatory assist devices in a large population of chronic heart failure patients who are not sick enough to justify being implanted with a full support ventricular assist device (VADs) but who have tried all other less invasive options without success. Traditional ventricular assist devices provide full support, taking over the work of the heart's main pumping chamber in end-stage heart failure patients in or near cardiogenic shock. Their use is restricted because the surgery required for their insertion is major, invasive and risky.

"Traditional VADs pump five to seven liters of blood per minute and therefore, just by physical necessity, they have to be large," said Daniel Burkhoff, M.D., Ph.D, adjunct associate professor at Columbia University, New York, and chief medical officer of CircuLite, Inc., developer of the Synergy device. "Synergy, the smallest device being investigated in adults, supports cardiac function by pumping just 2.5 to 3.0 liters of blood per minute."

"This study was done to determine if such partial support would be adequate to provide long-term benefits in NYHA Class IIIb and early Class IV patients."

In the study, 16 patients (13 males), mean age 52 years, with a mean baseline ejection fraction of 20 percent, were implanted with the Synergy™ pump. Before implantation, their mean arterial pressure was 71 mmHg, mean pulmonary capillary wedge pressure was 29 mmHg, and mean cardiac index was 1.9 L/min/m^2. The duration of their partial support was a median 81 days and ranged from six to 213 days.

Thirteen of the 16 patients (81 percent) were alive at three months. Of these, seven patients had right heart catheterization at 10.6 ± 6 weeks. Increases in mean arterial pressure (70 ± 6 mmHg vs 80 ±10 mmHg, p = 0.04) and cardiac index (2.1 ± 0.4 vs. 2.9 ± 0.6, p = 0.02) with large reductions in capillary wedge pressure (30 ± 5 vs. 16 ± 4, p = 0.002) were observed. Peak VO2 increased by 3.0 ± 0.5 ml/kg/min (10.7 ± 2.2 vs. 13.7 ± 2.2, p = 0.008).

"Prior studies have shown that when you implant a full ventricular support device, patients' hemodynamic function and heart function improve. The significance of this research is that we have shown for the first time that with long-term partial circulatory support, patients' hemodynamic condition is significantly improved and these improvements are sustained over time," Burkhoff said. "This is real proof of concept that the use of partial circulatory support is feasible and likely to be clinically meaningful. The ultimate goal is to use partial circulatory support not as a bridge to transplant, but as a long-term therapy. In Europe, the distinction between bridge to transplant and long-term support is blurred because the wait times are so long for a heart that patients can be supported for six to 24 months or more, even in a bridge situation."

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