カテーテル弁置換術の安全性は開心術と同様である（Abstract # 13-LB-15857）

PARTNER: 脳卒中および死亡は経カテーテル的大動脈弁置換術と標準的な手術とで同等である

PARTNER: Midterm stroke and death rates comparable for transaortic valve replacement and standard surgery

高リスク高齢者において経カテーテル的大動脈弁置換術（TAVR）の3年後の総死亡率および心血管死亡率は開心術と比較し同等であり術後30日間の脳卒中リスクも上昇しないとのレイトブレイキング臨床試験の結果が第62回American College of Cardiology学会で発表された。第Ⅲ相多施設スタディPARTNERでは、高リスクのfaulty大動脈弁患者699人を標準治療（351人）またはTAVR群（348人）に割り付けた。3年後の総死亡率は両群間でほぼ同等であった：標準手術群44.8%に対しTAVR群44.2%。心血管死亡率もまた標準手術群で30.2%およびTAVR群で30.1%であり、統計学的には差がつかなかった。両群ともに症状は同様に改善し、それは3年間持続した。2年後または3年後の脳卒中リスクにも差はなかった。TAVR脳卒中率は1年後で6%、2年後では7.7%であり3年後では8.2%であったのに対し、標準的な手術ではそれぞれ3.2%、4.9%および9.3%であった。このスタディは*American Journal of Medicine*オンライン版で公表されており2013年8月号印刷版に掲載予定である。

Full Text

All-cause and cardiovascular mortality were similar for transaortic valve replacement compared to open-heart surgery in high-risk older patients at three years with no increased risk of stroke after 30 days, according to results from the PARTNER study presented at the American College of Cardiology's 62nd Annual Scientific Session.

The transcatheter aortic valve replacement (TAVR) system was investigated as an alternative to open-heart surgery for high-risk patients with severe aortic stenosis. Recovery from catheter-based valve replacement typically takes a few days compared with four to eight weeks for open-heart surgery, which may be a benefit in a high-risk patient population.

The multi-center PARTNER study assigned 699 high-risk patients with faulty aortic valves to standard surgery (351 patients) or TAVR (348 patients). At three years, all-cause mortality was nearly identical in both groups: 44.8 percent for standard surgery compared to 44.2 percent for TAVR. Cardiovascular mortality rates also were statistically indistinguishable at 30.2 percent for standard surgery and 30.1 percent for TAVR. Both groups displayed similar improvements in symptoms that have been maintained for three years.

"One of the concerns has been the durability of the valve, but there seems to be no structural deterioration thus far," said Vinod H. Thourani, M.D., associate professor of cardiac surgery and co-director of the Structural Heart and Valve Center at Emory University School of Medicine in Atlanta. "It works as it's supposed to work, and hemodynamic performance is excellent past the three-year mark and comparable to surgical valve replacement."

With the much higher stroke rate reported for TAVR at 30 days, the other concern in this study has been whether a higher stroke risk would persist beyond that 30-day periprocedural window. None appeared at two or three years. TAVR stroke rates were 6 percent at one year, 7.7 percent at two years and 8.2 percent at three years, compared with 3.2 percent, 4.9 percent and 9.3 percent for standard surgery.

"After 30 days, TAVR patients don't have that many strokes," Dr. Thourani said. "At three years the surgery group's stroke rate has caught up with and slightly surpassed the TAVR rate but not to statistical significance."

Leaks around the valve were common soon after the procedure and were overwhelmingly higher in the TAVR group, and even mild aortic leakage is associated with a higher mortality rate after any valve replacement procedure, Dr. Thourani noted.

"In these first-generation transcatheter procedures, we have equivalent midterm outcomes between TAVR and the gold-standard surgical valve replacement in high-risk patients with severe aortic stenosis," Dr. Thourani said. "However, paravalvular leak continues to increase mortality at three years. Physicians should adopt innovative imaging technologies for more accurate sizing to help decrease these leak rates during TAVR."

The phase III study will follow patients for five years to assess durability of the TAVR device and longer-term outcomes.

Edwards Lifesciences sponsored this clinical trial and provides funding to Emory University for the research. Dr. Thourani sits on the steering committee and the publications committee for the PARTNER study.

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