中等度リスクの患者においてTAVRは手術に代わる妥当な代替療法である(LBCT 401-15)

PARTNER 2A：2年後の死亡率および脳卒中発症率は手術とTAVRとで同等である

PARTNER 2A: Rates of death and stoke equivalent for surgery and TAVR at two years

重度の大動脈弁狭窄を有し、非侵襲的経カテーテル大動脈弁置換術（TAVR）を施行された中等度リスク患者における2年後の死亡率および機能障害を残す脳卒中の発症率は、標準的な開心術による大動脈弁置換術を施行された患者と同等である、と第65回American College of Cardiology年次集会で発表され、同時に*New England Journal of Medicine*に掲載された。この非劣性試験の追加データから、経大腿動脈アプローチで施行された場合にはTAVRの方が優れている可能性があることが示唆された。TAVRを施行された患者はまた、手術を施行された患者に比べ入院期間が短く一部の主要合併症も少なかった。

Full Text

Intermediate-risk patients with severe aortic stenosis who receive minimally invasive transcatheter aortic valve replacement, known as TAVR, have similar rates of death and disabling strokes after two years compared with those undergoing standard open heart surgical replacement, according to a study presented at the American College of Cardiology's 65th Annual Scientific Session and simultaneously published online in *The New England Journal of Medicine*. Patients receiving TAVR also experienced shorter hospital stays and lower incidence of some major complications compared with those undergoing surgery.

Data from this non-inferiority trial—the first to evaluate TAVR in patients who are considered intermediate-risk—suggests TAVR is at least as safe and effective as surgery in these patients. Overall, the primary endpoint of all-cause death and disabling strokes was comparable at two years, 19.3 percent for TAVR and 21.1 percent for surgery. Among TAVR patients with transfemoral placement of the valve—the least invasive of two approaches in which the device is implanted through a small incision in the groin—the combined rate of death and disabling stroke was lower, 16.8 for TAVR compared with 20.4 percent for surgery (p-value=0.05).

"For the past five years, TAVR has been growing in use and acceptance largely based upon clinical evidence from multiple randomized controlled trials, but these have been limited to patients at the highest risk for surgery," said Martin B. Leon, M.D., professor of medicine and director of the Center for Interventional Vascular Therapy at Columbia University Medical Center-New York Presbyterian Hospital and co-principal investigator of the PARTNER trials. "Here, we demonstrate outcomes related to death and stroke, which are equivalent in these patients and may be superior in the transfemoral group."

To perform TAVR, a surgeon threads a replacement valve to the heart through a catheter placed in the groin or chest. TAVR is currently approved for patients with severe aortic stenosis whose health profile makes them ineligible or high-risk candidates for open-heart valve replacement surgery.

In this randomized controlled PARTNER 2A trial, outcomes using the SAPIEN XT valve were compared with open-heart surgery valve replacement among 2,032 intermediate-risk patients treated between December 2011 and November 2013 at 57 sites, all but two in the U.S. Patients were randomly assigned; 1,011 to TAVR and 1,021 to surgery. Of those in the TAVR group, 76 percent underwent transfemoral placement, and the rest had transthoracic placement in which the new valve is thread through a cut in the chest wall.

"When we compare transthoracic TAVR patients to those having surgery, they are about the same, so whatever benefit achieved related to lower rates of death and strokes was clearly in the transfemoral group," Leon said.

Researchers also found significant differences in secondary clinical endpoints looking at time in the hospital, valve function and major complications, some favoring TAVR, some surgery. For example, TAVR patients spent less time in the hospital overall—the average time in the ICU was two days with TAVR versus four days with surgery, and the average hospitalization for TAVR was six days compared to nine days with surgery. TAVR also appeared to improve the aortic valve areas more than surgery, meaning that the quality of the valve's performance was better as measured by echocardiography during follow-up points through two years.

Compared to surgery, TAVR also yielded significantly lower rates of acute kidney injury, severe bleeding events and new onset atrial fibrillation, a heart rhythm problem that is a common complication of open procedures. The surgery group, on the other hand, had fewer major vascular complications and leakage around the valve (para-valvular regurgitation).

The heart team discussed each individual case to determine if patients were indeed intermediate-risk. Baseline characteristics were comparable. All patients were followed for at least two years and will continue to be followed for five years.

"The two-year follow-up allows enough time to accurately assess the relative performance of these two valve replacement therapies," Leon said, adding that he suspects these findings will potentially affect clinical guidelines for TAVR in the future. "We know surgery is good, but it is still a major procedure and for many patients, a less-invasive approach may be the preferred alternative. As we continue to evolve the procedure and technology, it's important to know whether TAVR is an effective alternative in these lower risk patients."

The study was funded by Edwards LifeSciences.

The SAPIEN XT device used in this trial is an older model transcatheter. The same research team will present findings comparing the SAPIEN 3, the newest generation of the device, to surgery.

ACC2016特集