カテーテルを用いた大動脈弁手術の開心術に対する非劣性が認められた

PARTNER：新たな心臓弁システムと標準的な手術の1年生存率は同等である

PARTNER: Survival similar at one year for novel heart valve system and standard surgery

高齢ハイリスク患者に対する経カテーテル大動脈弁置換術（TAVR）と従来の開心大動脈弁置換（AVR）術を比較した結果、脳卒中や重大な出血などのエンドポイントには差があったが、1年死亡率は同等であったとのPARTNERトライアルの結果が第60回American College of Cardiology学会で発表された。重度大動脈弁狭窄を有するハイリスク高齢患者計699人を26施設においてTAVRまたはAVRに無作為に割り付けた（TAVR348人；AVR350人）。年齢中央値は84.1歳であった。30日間の総死亡率（3.4%対6.5%）および症状改善率はTAVRの方が良好であったが、これらの確率は1年後には同等になった。重大な脳卒中発現率は、30日間（3.8%対2.1%）および1年間（5.1%対2.4%）ともにTAVRにおいて高かった。30日間の主要な血管系合併症もまたTAVR後においてかなり多く認められた（11.0%対3.2%）が、重大な出血の発現率（9.3%対19.5%）および心房細動による不規則な心調律の新規発症（8.6%対16.0%）はTAVR群においてはるかに低かった。人工弁周囲逆流もまた、TAVR後により多く認められた。

Full Text

Death rates are similar at one year for a catheter-based method of replacing heart valves and conventional surgery in older high-risk patients, though endpoints such as stroke and major bleeding show marked differences, according to research from the PARTNER Trial presented at the American College of Cardiology's 60th Annual Scientific Session.

Standard treatment for severe stenosis is open-heart surgery to replace the aortic valve (AVR), but many older people are medically unfit for the procedure. Without valve replacement, half of these patients die within two years.

This is the first report from a randomized trial of AVR versus a minimally invasive system called transcatheter aortic valve replacement (TAVR) in AVR candidates whose age and overall health posed high risks for conventional surgery. In previously reported findings for patients in this trial who were not candidates for AVR, TAVR was linked to a 20 percent survival benefit at one year.

"Large-scale, randomized comparisons of new interventional procedures to gold-standard surgical procedures have seldom been done," said Craig R. Smith, M.D., chief of the Division of Cardiothoracic Surgery, New York-Presbyterian Hospital/Columbia University Medical Center, and the study's co-principal investigator. "This is the ideal opportunity, because surgical AVR is one of the most effective operations surgeons offer, and TAVR is the most exciting new treatment for aortic stenosis in the past two to three decades."

TAVR's centerpiece is a wire mesh stent encasing three sutured-on valve flaps called leaflets, made from cow tissue and treated to cut down on calcium deposits that cause stenosis. Cardiologists deliver the bioprosthetic valve to its target location with a catheter guided transfemoral (TF) or transapical (TA) access if peripheral arteries are not large enough. Like standard valve replacement, this procedure is performed under general anesthesia.

A total of 699 high-risk older patients with severe aortic stenosis were randomly assigned at 26 centers to TAVR or to AVR. The median age was 84.1 years. The TAVR group totaled 348 patients (244 TF, 104 TA); 350 patients were in the AVR group. Patient characteristics were similar overall across cohorts, but the patients assigned to TA TAVR had a higher risk profile. Endpoints included death from any cause at one year (primary endpoint), stroke and major vascular and bleeding events.

Although 30-day results favored TAVR for all-cause deaths (3.4 percent vs. 6.5 percent) and improvement in symptoms, both rates were similar at one year. Major strokes were higher for TAVR at both 30 days (3.8 percent vs. 2.1 percent) and one year (5.1 percent vs. 2.4 percent). At 30 days major vascular complications also were much more common after TAVR (11.0 percent vs. 3.2 percent), but the TAVR group's rates were much lower for major bleeding (9.3 percent vs. 19.5 percent) and new-onset irregular heart rhythms of atrial fibrillation (8.6 percent vs. 16.0 percent). Para-valvular regurgitation - leaks alongside or near the valve ? occurred more often after TAVR as well.

"These results clearly show that TAVR is an excellent alternative to surgical AVR in high-risk patients," Smith said. "Recommendations to individual patients will need to weigh the appeal of avoiding open-heart surgery, with its known risks, against less invasive TAVR with different and less well understood risks, as well as the absence of long term follow-up. Future trials will help delineate the role of TAVR in intermediate risk patients."

A follow-up PARTNER II Trial was approved in February 2011 to test the next generation of this novel valve and a different catheter delivery system against the valve and delivery method used in the first PARTNER Trial.

The trial is funded by Edwards Lifesciences, Inc. Smith has no financial relationship with the company.

ACC2011特集