CoreValveの2年間の優位性が確認された (Abstract 404-12)

CoreValve：高リスク患者において自己拡張型TAVRは延命効果が2年間にわたり手術よりも優れていた

CoreValve: Self-expanding TAVR widens survival advantage over surgery at two years in high-risk patients

2年間のデータから、重度の大動脈弁狭窄を有する高リスク患者において自己拡張型経カテーテル大動脈弁置換術（TAVR）は標準的な手術よりも延命効果に優れていたことが示された、との研究結果が第64回American College of Cardiology年次集会で発表された。CoreValve U.S. Pivotal High Risk Trialにおいて、開心弁置換術によるリスクの高い患者がTAVRまたは標準的な手術を施行される群にランダムに割り付けられた。1年後の死亡率は、TAVR群390人において開心術を受けた357人よりも有意に低かった。TAVRにおける延命効果は2年後に増大していることが明らかにされた—2群間の総死亡率の絶対差は拡大し、生存患者は1年後の時点ではTAVR群において手術群より4.8%多く、2年後にはTAVR群患者の方が手術群患者よりも6.4%多かった。自己拡張型デバイスはまた、他のエンドポイント発現率も低かった。脳卒中発現率はTAVR患者における10.9%に対し手術群では16.6%であり、重大な心血管または脳血管イベント発現率はTAVR群の29.7%に対し手術群では38.6%であった。

Full Text

Two-year data show a continued survival advantage for self-expanding transcatheter aortic valve replacement (TAVR) over standard surgery in high-risk patients with severe aortic stenosis, according to research presented at the American College of Cardiology's 64th Annual Scientific Session.

In the CoreValve U.S. Pivotal High Risk Trial, patients with a heightened risk of death from open-heart valve replacement were randomly assigned to TAVR or the standard surgical procedure. Death rates at one year were significantly lower for the 390 TAVR patients than for the 357 patients who had open-heart surgery. Year two data include three more patients, two of whom received a smaller second-generation CoreValve that wasn't available earlier.

"Survival is statistically better with TAVR and sustained at two years," said Michael J. Reardon, M.D., professor and Allison Family Chair of Cardiovascular Research at Houston Methodist Hospital and the study's lead author. "We found that the survival advantage actually increases for TAVR—that the absolute difference in all-cause death rates between the two groups has widened, with 4.8 percent more people surviving with TAVR than surgery at one year and 6.4 percent more surviving with TAVR at two years."

The self-expanding device also had significantly lower rates for other endpoints. The rate of strokes was 10.9 percent for TAVR patients and 16.6 percent for surgery patients, and 29.7 percent of TAVR patients had a major adverse cardiovascular or cerebrovascular event compared with 38.6 percent of surgery patients. Results favored TAVR across all subgroups analyzed.

"Durability is an issue, and we saw no evidence of TAVR valve deterioration," Reardon said. "Effective valve orifice and mean pressure gradients [measures of valve quality] were statistically superior with TAVR at every time point during the trial."

Leaking around the new valve is one area where surgery consistently performs better than TAVR in clinical trials.

"Moderate to severe paravalvular leakage with TAVR was low at one year at 6 percent and stayed low at two years at 6.1 percent," Reardon said, noting that, unlike some other TAVR studies, leaks haven't had an impact on mortality with this valve. "We had very few cases of moderate or more leaks, and this may be why we don't see a mortality signal with leakage."

With these latest findings, Reardon sees reason to revisit current guidelines.
"This trial moves the field forward in that ACC/AHA guidelines state that TAVR is a reasonable alternative to surgical valve replacement in high-risk patients, as judged appropriate by the heart team," he said. "This trial's data suggest that TAVR with the self-expanding valve should be the preferred treatment in patients with symptomatic severe aortic stenosis at increased risk from surgery."

Acknowledging that these are early findings, he said that longer follow-up is needed to confirm that this valve continues to demonstrate benefits over surgery. The CoreValve High Risk trial will follow patients for five years.

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