自己拡張型TAVRを用いた際の死亡は手術と比較し少ない

CoreValue：主要試験において大動脈弁狭窄に対する自己拡張型経カテーテル大動脈弁は手術よりも優れていた

CoreValue: Self-expanding transcatheter aortic valve better than surgery for aortic stenosis in pivotal trial

重度大動脈弁狭窄を有する高リスク患者において、自己拡張型弁置換術を用いた経カテーテル大動脈弁置換術（TAVR）は従来の手術と比較し1年間の死亡率が有意に低いことが初めて示されたとの研究結果が、第63回American College of Cardiology学会で発表され、*New England Journal of Medicine*オンライン版に掲載された。CoreValve U.S. Pivotal High Risk Trialは、リスク評価にて大動脈弁手術による死亡リスクが高い患者を組み入れた。795人の患者がカテーテルまたは手術による弁置換術を施行される群にランダムに割り付けられ、747人がどちらかの施術を受けた（TAVR群390人および外科的大動脈弁手術群357人）。両群ともに平均年齢は83歳であった。その結果、初回非劣性ゴールを超えていたため、既にデザインされていた優位性解析へと移行した。30日間の死亡率には有意差はなかった（TAVR 3.3%対手術4.5%）。有意差は一次エンドポイントである1年間の総死亡において発現した（TAVR 14.2%対手術19.1%）。予備解析では、1年間の心筋梗塞、脳卒中またはこれらの関連死はTAVRで有意に低い（20.4%対27.3% ）ことも示された。

Full Text

Transcatheter aortic valve replacement with a self-expanding valve prosthesis for the first time has demonstrated significantly lower death rates at one year compared with conventional surgical valve replacement in high-risk patients with severe aortic stenosis, according to research presented at the American College of Cardiology's 63rd Annual Scientific Session and simultaneously published online in the *New England Journal of Medicine*.

Worldwide, an estimated 300,000 people have severe aortic stenosis and roughly a third of them are deemed unable to withstand the standard treatment of open-heart surgery to replace the valve. But if the condition is left untreated, risk of death is 25 percent the first year after symptoms appear and rises to 50 percent the second year. Replacement valves delivered by a catheter have been developed as a less invasive alternative to open-heart surgery.

The CoreValve U.S. Pivotal High Risk Trial enrolled patients with an assessed increased risk of death from aortic valve surgery. Of 795 patients randomly assigned to valve replacement by catheter or surgery, 747 patients underwent one of the procedures: 390 in the transcatheter aortic valve replacement (TAVR) arm and 357 in the surgical aortic valve replacement arm. The average age was about 83 years in both groups. The results exceeded the initial non-inferiority goal and, by pre-design, then moved on to a superiority analysis. Death rates at 30 days were not significantly different, with a 3.3 percent death rate for TAVR and 4.5 percent for surgery. A significant difference emerged at the one-year primary endpoint of all-cause mortality: 14.2 percent for TAVR with CoreValve compared with 19.1 percent for surgical replacement.

"This is the first prospective study of any device that suggests TAVR is superior to [surgery] in a predefined population of patients, and that's a provocative finding," said David H. Adams, M.D., professor and chairman of the Department of Cardiothoracic Surgery at Mount Sinai Medical Center and co-principal investigator of the study. He emphasized the "outstanding outcomes" in the surgical arm: "The low mortality rates with conventional surgery far exceeded the predicted mortality according to the Society of Thoracic Surgeons predictive model. In order to pass a superiority threshold, transcatheter treatment with the CoreValve device had to exceed excellent surgical outcomes."

Exploratory analyses also showed the one-year rate for heart attack, stroke or related death was significantly lower for TAVR at 20.4 percent compared with 27.3 percent for surgical replacement.

"We also performed multiple different subgroup analyses for one-year death rates and found the survival benefit of TAVR with CoreValve was consistent across all clinical subgroups we examined, regardless of thresholds," Adams said.

The 30-day observed death rates for TAVR and surgical valve replacement were much lower than the anticipated rate of 15 percent, Adams said, suggesting that the patient population may have had lower risks than intended. In addition to the STS score, frailty and other disabilities were considered in the evaluation of risk. Randomization ensured a robust trial nonetheless, he said, adding that this study confirmed that current risk assessment models, including expert physician reviews, overestimate contemporary surgical risks.

A potential limitation of the study is the higher dropout rate for patients randomly assigned to surgery, as reported with previous TAVR trials. Forty patients assigned to surgery dropped out of the study before treatment, while only four assigned to the TAVR arm dropped out. The trial was designed with this anticipated attrition rate, and a sensitivity analysis confirmed that there were no significant differences in the risk profiles between patients who underwent the assigned surgical treatment and those who withdrew, Adams said.

"We are confident that the higher withdrawal rate in the surgical arm did not affect our findings," he said.

The study was funded by Medtronic, Inc. The Icahn School of Medicine at Mount Sinai receives royalties for intellectual property developed by Adams for mitral and tricuspid repair products now owned by Edwards Lifesciences and Medtronic.

ACC2014特集

[News01]
セリアック病は冠動脈疾患リスクを上昇させる

[News02]
宇宙において宇宙飛行士の心臓はより球状になる

[News03]
スタチンは勃起不全の症状を改善する

[News04]
出産した子供の数は女性の将来の心血管系の健康状態に影響する

[News05]
腎除神経術は治療抵抗性高血圧に有益性をもたらさない

[News06]
クロニジンは相殺による有益性はもたらさずリスクを上昇させる

[News07]
非心臓手術周術期のアスピリン使用は重大な出血を増加させる

[News08]
糖尿病管理目的の肥満手術の持続的効果

[News09]
血液バイオマーカーがMI否定に有望であることが示された

[News10]
自己拡張型TAVRを用いた際の死亡は手術と比較し少ない

[News11]
STEMIにおいてヘパリンはbivalirudinよりも優れている

[News12]
モノクローナル抗体阻害とスタチンの組み合わせのLDL-Cに関する評価

[News13]
抗PCSK9抗体薬はLDLコレステロール低下に有効である

[News14]
ステント留置後抗凝固療法の個別化によりMIおよび死亡リスクが低下した

[News15]
ビタミンD欠乏はより重篤な心疾患と関連する

[News16]
心臓再同期療法は心不全の生存率を改善する