

## 中等度リスク患者に対するTAVIの有効性 (LBCT.02)

GARY: 中等度リスク患者においてTAVIの死亡率はSAVRより高い

GARY: TAVI mortality higher versus SAVR in intermediate risk patients

ドイツのレジストリにおける手術リスク中等度の大動脈弁狭窄症患者において、1年後の調整死亡率は経カテーテル大動脈弁留置術(TAVI)施行患者において、外科的大動脈弁置換術(SAVR)施行患者に比べ有意に高かった、と2016年American Heart Association学術集会で発表された。院内死亡率はTAVI患者で3.8%、SAVR患者で2.6%であり、1年後の死亡率はTAVIで16.6%、SAVRで8.9%であった。この2群間の有意な死亡率の差は、傾向スコア解析後でも認められた。しかし、レジストリデータの後ろ向き解析は、2つの治療戦略を比較する選択法ではない、と筆者らは指摘している。

### Full Text

Transcatheter aortic valve implantation (TAVI) is currently the recommended treatment for patients with severe aortic valve stenosis who have high surgical risk. At present, there is little real-world data from smaller studies available on patients at intermediate surgical risk with regard to indications and outcome of TAVI versus surgical aortic valve replacement (SAVR).

This analysis from the German Aortic Valve Registry (GARY), a large real-world multicenter registry, compares the efficacy and outcomes of intermediate-risk patients who were treated by transcatheter aortic valve implantation or conventional surgical aortic valve replacement in Germany over three years in daily clinical practice. The analysis was reported by Nicolas Werner, M.D. Medizinische Klinik B, Ludwigshafen, Germany at the American Heart Association 2016 Scientific Sessions.

A total of 5,997 patients at intermediate surgical risk underwent isolated transcatheter aortic valve implantation (4,101) or surgical aortic valve replacement (1,896) at 88 sites in Germany between 2011 and 2013. Patients treated by TAVI were significantly different in baseline characteristics (older, more often female and had higher risk scores) from patients treated by surgical aortic valve replacement – revealing a marked selection bias that cannot completely be adjusted for and which led to different clinical outcomes.

In-hospital and one-year death rates were significantly higher in transcatheter aortic valve implantation patients than in surgical aortic valve replacement patients: 3.8 percent for in hospital TAVI patients versus 2.6 among in hospital surgical patients and 16.6 percent at one year after TAVI versus 8.9 percent one year after surgical replacement. The unadjusted death rate was higher after TAVI, and a significant difference in one-year mortality rate persisted between the two groups even after propensity score analysis.

For differences in specific complication rates between TAVI and surgical aortic valve replacement, an individualized therapeutic decision by a dedicated Heart Team, based on the clinical situation of the patient and the associated procedural risk may be the best approach for the group of patients at intermediate surgical risk, researchers said. However, they noted, retrospective analysis from registry data is not the method of choice to compare two treatment strategies. This should only be done by randomized controlled trials.

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