TAVRとともに用いられるfirst-in-field脳フィルターの有益性が認められた (Abstract 404-16)

DEFLECT Ⅲ：弁置換術の際に遊離する粒子を防御するデバイスが予後を改善した

DEFLECT III: Device that deflects particles dislodged during valve replacement improves outcomes

経カテーテル大動脈弁置換術（TAVR）中の組織砕片を脳から偏向させる試験的デバイスは院内安全性転帰および退院時認知スコアを改善するようであるとの小規模ランダム化スタディの予備的な結果が第64回American College of Cardiology年次集会で発表された。DEFLECT IIIトライアルにおいて調査されたデバイスTriGuardは、脳への3つの血管を一時的にメッシュフィルターで覆うことにより、有害な可能性のある組織砕片を遊離させるTAVRおよび他の施術中の脳損傷リスクを軽減させるようにデザインされた。83人の患者において計測された予備的な院内安全性および有効性が報告された。TAVR後7日間までの重大な階層的複合心血管および脳血管有害イベントとして定義した院内施術安全性に関しては、このデバイスを使用された患者では22.2%でありコントロール群では31.6%であった。総死亡率はデバイス群で2.2%であり、コントロール群では5.3%であった。脳卒中および生命の危険のあるまたは障害を残す出血の両者に関しては、デバイス群で2.2%でありコントロール群で5.3%であった。

Full Text

An investigational device that deflects debris away from the brain during transcatheter aortic valve replacement (TAVR) seems to improve in-hospital safety outcomes and cognitive scores at discharge, according to preliminary findings from a small randomized study presented at the American College of Cardiology's 64th Annual Scientific Session.

The valve replacement procedure dislodges minute particles from the clogged valve, freeing them to float through the bloodstream. Much of this debris travels "downstream" from the heart, but about a quarter of the debris moves "upstream" to the brain, where it can trigger a stroke or other damage. These microscopic scraps are a likely contributor to the high stroke rates seen up to a year after TAVR and to the high rates of subclinical brain injury—damage less severe than a stroke that can affect mental functions.

TriGuard, the device being studied in this trial, the DEFLECT III trial, was designed to reduce the risk of brain damage during TAVR and other procedures that release potentially hazardous debris by covering the three arteries that lead to the brain with a temporary mesh shield.

Preliminary data are available for 83 patients with complete in-hospital safety and efficacy measures. Thirty-day data are being gathered and are expected to be reported in May. Target enrollment for the trial is 86 patients recruited from 15 centers in Europe and Israel.

The novel device demonstrated benefit on several endpoints in this small patient population. For in-hospital procedure safety, defined as a hierarchical composite of major adverse cardiovascular and cerebrovascular events up to seven days after TAVR, the rates were 22.2 percent for patients with the device and 31.6 percent for patients in the control group.

Death rates from all causes were 2.2 percent for the device group and 5.3 percent for the control group. For both stroke and life-threatening or disabling bleeding, rates were 2.2 percent for the device group and 5.3 percent for the control group. No safety concerns were seen in two categories: rates of acute kidney injury were 2.2 percent for the device group compared with 0 for the control group—one patient vs. none; and rates of major vascular complications were 15.6 percent for the device group and 15.8 percent for the control group.

"Protecting the brain has become a priority to improve our patients' outcomes, and this is a new focus in interventional cardiology," said Alexandra J. Lansky, M.D., director of the Yale Cardiovascular Research Program, Yale School of Medicine and the study's lead author. DEFLECT III is the first multicenter randomized clinical trial of a brain-protection device.

Lansky said patients in the protected group performed better than the control on two cognitive tests, the Montreal Cognitive Assessment, which takes a broad look at all domains of neurocognition, and the Cogstate test, a computerized assessment of mental processing. Diffusion weighted MRI, used as a surrogate endpoint for subclinical brain injury, showed that fewer patients in the device group had new brain lesions and that the volume of the lesions was lower than in the control group.

Patients will be followed for 30 days, and all neurocognition and weighted imaging measures will be repeated at that point to determine whether the early benefits continue. The FDA has approved a definitive Investigational Device Exemption trial called REFLECT, which is expected to start enrollment during the second quarter of 2015.

This trial was sponsored by Keystone Heart Ltd. Lansky has a minor ownership in the company.

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