Multispecialty Outpatient Cardiovascular Association

June Edition

Investigators find small reduction in disabling stroke from embolic protection device use

Neel Butala (University of Colorado, Aurora, USA) presented these conclusions during a late-breaking clinical trials and science session at New York Valves (5–7 June, New York, USA), following what was described as the largest analysis to date of outcomes following the use of cerebral embolic protection following TAVI. Findings of the study were also published in *Circulation: Cardiovascular Interventions*.Cerebral embolic protection devices are intended to mitigate the risk of stroke during TAVI by capturing and removing debris dislodged during the procedure before it reaches the brain, however their benefit remains unproven.

The largest trial so far to investigate the use of a cerebral embolic protection device, the PROTECTED TAVR trial which assessed Boston Scientific's Sentinel, found no significant effect on the incidence of periprocedural stroke, but a difference in rates of disabling stroke which favoured the use of cerebral embolic protection.

Using the Society of Thoracic Surgeons (STS) and American College of Cardiology (ACC)-established TVT registry, which monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures performed throughout the USA, Butala and colleagues set out to examine the association between embolic protection device use and a proxy for disabling stroke among transfemoral TAVI patients between 2018 and mid-2023.

Of note, the research showed a steady growth in embolic protection device usage throughout the duration of the study followed by a decline and plateau coinciding with the release of the PROTECTED TAVR trial results. In mid-2023, embolic protection devices were used in 34% of hospitals and 12% of patients, with marked variation between centres. Butala reported. https://cardiovascularnews.com/small-reduction-disabling-stroke-embolic-protection-device/

FYI:

- **Top news stories from AMA Morning Rounds®: Week of June 3, 2024**

Cardiac-MRI data from DurAVR FIH study shared at New York

DurAVR is a balloon-expandable, single-piece transcatheter aortic valve shaped to mimic the performance of a native human aortic valve. Joao Cavalcante (Allina Health Minneapolis Heart Institute, Minneapolis, USA) presented the new MRI data, which showed excellent post-procedure haemodynamic results in 41 patients, with large effective orifice areas (2.2cm2), single-digit mean gradients (8.5mmHg) and a Doppler Velocity Index (DVI) of 0.62.
Cavalcante commented: "When we look at commercially available surgical or transcatheter aortic valve implantation (TAVI) valves, we are still seeing abnormal flow patterns on cardiac MRI. The restoration of laminar flow, as we are seeing with this new DurAVR THV, is a byproduct of the intrinsic valve design and novel technology, which might have positive downstream implications to the arteries and consequently to ventricle, and ultimately to the patients."
https://cardiovascularnews.com/cardiac-mri-data-duravr-fih/

DynamX sirolimus-eluting bioadaptor system gains US FDA breakthrough designation

The breakthrough designation is for an indication to improve coronary luminal diameter, restore haemodynamic modulation, and reduce plaque progression in patients with symptomatic ischaemic heart disease due to discrete de novo native coronary artery lesions.
The DynamX bioadaptor has a novel design and mechanism of action designed to return the diseased vessel to a more normal condition, through three distinct phases. After implantation, the locked phase establishes the maximum flow lumen and restores blood flow to treat symptoms of coronary artery disease (CAD).

Unique to the bioadaptor, the second phase occurs after the bioadaptor is encapsulated with tissue and the absorbable polymer coating is resorbed. This enables the bioadaptor helical strands to unlock and separate, releasing and allowing the vessel to grow and adapt to maintain the established blood flow lumen.

The third and most unique phase provides the vessel adaptive dynamic support by the separated helical strands. This restores the vessel viability and hemodynamic modulation by returning pulsatility, compliance, adaptive blood flow volume, and plaque stabilization and regression.

FDA breakthrough device designation accelerates the review process for novel technologies that may provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, such as CAD, which impacts 7.8% of the US population.

To date, interventional treatment of coronary artery disease with drug-eluting stents has been able to establish flow angiographically. However, up to 20% of patients experience a repeat adverse event related to the implant within five years of treatment. https://cardiovascularnews.com/dynamx-us-fda-breakthrough-designation/

Six-month TANDEM I results "promising" for Duo tricuspid coaptation system

The Duo system is a novel transcatheter coaptation valve that works in tandem with the native tricuspid valve to restore valve function, using an anchor system which leaves the right heart and native valve apparatus untouched**.**

Wojciech Wojakowski (Medical University of Silesia, Katowice, Poland) presented the results of the prospective, non-randomised, multicentre study designed to evaluate the safety and performance of the Duo system in patients with severe symptomatic TR. The study reported on 10 patients enrolled, showing sustained positive outcomes.

Following 30-day outcomes presented last year, the six-month results demonstrated significant TR reduction by an independent core lab assessment, with TR reduced to moderate or less in over 85% of patients, even with massive or torrential TR at baseline.

Patients also experienced markedly improved functional and quality of life outcomes, with a notable significant increase in both Kansas City Cardiomyopathy Questionnaire (KCCQ) score and six-minute walk test (6MWT) over baseline.

https://cardiovascularnews.com/six-month-tandem-i-results-croivalve/

DeepQure receives IDE approval of extravascular renal denervation system to treat resistant hypertension

The company describes HyperQure as the world's first extravascular renal denervation device for the treatment of resistant hypertension.

With this approval, the company will commence the early feasibility study (EFS) to prove the safety and efficacy of HyperQure in 15 patients with resistant hypertension. The clinical trial will be conducted in a prospective, multicentre, single-arm, open-label design at major US university hospitals, including Stanford University, Mayo Clinic, Emory University, University of Arizona and the University of California, Irvine.

"We are thrilled that the FDA has approved our IDE study plan. This is a significant US regulatory milestone for DeepQure, starting the feasibility study using the extravascular ablation platform in the USA for the renal denervation indication. We will accelerate our global clinical trials with this IDE approval," says Chang Wook Jeong, co-founder and chief medical officer of DeepQure.

https://cardiovascularnews.com/deepqure-ide-approval/

Upcoming:

- *Next Meeting: July or August- Keep an eye out for date!*
- *Have an interesting case you'd like to share with the group? Contact Sarah Cook to be the next M & M Speaker to the MOCA Group!*