MEDTECH INSIGHT
CITELINE COMMERCIAL

14 Nov 2023 | **News**

News We're Watching: AHA Meeting In Philly; Surgeons Call For TAVR Caution; China Approves J&J's Monarch Robot

by Reed Miller

New clinical trial data presented at the American Heart Association Scientific Sessions in Philadelphia dominated the R&D news this week. Here are some of the highlights from the conference as well as some other bits of medtech industry news you may have missed.

Surgeons Insist TAVR May Not Be Best Choice For All Low-Risk Patients

The Society of Thoracic Surgeons (STS) and European Association for Cardio-Thoracic Surgery (EACTS) are recommending "caution" to patients, surgeons and interventionalists before adopting transcatheter aortic valve replacement (TAVR) as the first option for low-risk patients who need a new aortic valve.

New results from two major clinical trials suggested TAVR is a safe and effective alternative to surgery in patients at low risk for surgical complications. The safety and durability of TAVR is supported by four-year outcomes from the *Evolut Low-Risk trial* comparing *Medtronic*'s CoreValve TAVR systems to surgical aortic valve replacement in low-risk patients. Also, five-year results from the *PARTNER 3* trial showed similar durability for *Edwards Lifesciences*' Sapien 3 or Sapien 3 Ultra TAVR system in low-risk patients. (Also see "*News We're Watching: TCT Yields More Encouraging Results For TAVR; HeartPoint Resets Trial Plans, Butterfly Tries Brain-Interface Tech*" - Medtech Insight, 30 Oct, 2023.)

In a new joint statement, the surgeon groups argue that these results do not show that TAVR is superior to surgical valve replacement for all low-risk patients.

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“It is important to note that aortic valve replacement is largely an isolated procedure in transcatheter clinical practice, but up to 26% of the surgical patients in the PARTNER 3 and Evolut Low-Risk trials underwent concomitant procedures, including [coronary bypass] surgery,” the STS and EACTs argue.

The outcomes of concomitant operations are generally worse than the outcomes of isolated valve replacement procedures and patients with ischemic disease are not directly comparable to patients with isolated valve disease, the statement explain.

“While STS and EACTS fully respect the value of randomized evidence, we feel that this is only as good as the comparator groups.”

The statement also points out that, measured separately, all-cause mortality, cardiovascular mortality, and disabling stroke were not statistically significant between groups in the Evolut Low Risk trial. “Therefore, statements of superiority of [TAVR] compared to a heterogeneous surgical comparator, are not appropriate at this time and may lead to unintended consequences,” the societies argue.

“We call on investigators from both the PARTNER 3 and Evolut Low-Risk trials to publish their results for the isolated SAVR and isolated [TAVR] sub-cohorts from their trial arms,” STS/EACTS proposes. “Until we have this data, any statements or conclusions from these trials are interesting but still hypothesis generating and speculative.”

Cleerly Looks To TRANSFORM Personalized Heart Disease

Cleerly is sponsoring the *TRANSFORM* study of its proprietary system for quantitative analysis and staging of coronary atherosclerosis.

The company's coronary computed tomography angiography (CCTA) software, cleared by the US Food and Drug Administration in 2020, relies on machine-learning and 3D-imaging techniques to analyze, characterize, and quantify coronary disease to help their doctors prevent heart attacks.

TRANSFORM will enroll 7,500 people in the US with pre-diabetes, type 2 diabetes, or metabolic syndrome, but no symptoms of heart disease. The subjects will be randomized to "usual care" or examination with Cleerly's coronary artery disease staging system at baseline and at 24 months. (Also see "*Cleerly Advances CCTA Digital Pathway To Stop Heart Disease*" - Medtech Insight, 6 Dec, 2022.)

The subjects will be followed for an average of three and a half years and the primary endpoint is total adverse events – including cardiovascular death, non-fatal myocardial infarction, non-fatal ischemic stroke, non-fatal acute limb ischemia, clinically driven arterial revascularization, hospitalization or urgent hospital visit for heart failure.

The study is led by Deepak Bhatt of Mount Sinai Heart Hospital in New York, a well-known cardiologist and leader of major clinical trials. "This trial provides us the opportunity to revolutionize cardiovascular event prevention and ultimately save lives from heart disease," Bhatt said. "I eagerly anticipate the collaboration with all the valued partners across this trial and the forthcoming results to help us shape the future of cardiovascular care,"

TRANSFORM will start enrolling patients in early 2024, the recruitment is scheduled to close in late 2025, and the results will probably be available in 2028, Cleerly announced at the American Heart Association Scientific Sessions in Philadelphia on 11 November. More information is available at *transformtrial.org*.

Boston Scientific's Farapulse PFA Holds Up In Real-World Registry

Outcomes from MANIFEST 17K, a 17,000-patient registry of atrial fibrillation (AF) patients, support the "real-world" safety of *Boston Scientific*'s Farapulse pulsed field ablation (PFA) system.

Vivek Reddy of the Mount Sinai School of Medicine in New York presented the *MANIFEST 17K results* at the American Heart Association Scientific Sessions in Philadelphia on 11 November.

In the MANIFEST 17K data, there are no reports of permanent phrenic nerve palsy, pulmonary vein stenosis or esophageal injury, and an overall major adverse event rate of less than 1%. MANIFEST 17K builds on *ADVENT*, the first randomized trial of Farapulse, which met its primary and safety efficacy endpoints. (Also see "*News We're Watching: Philips And Walgreens Settlements, ReCor Readies For Takeoff, Farapulse Trial Results*" - Medtech Insight, 8 Sep, 2023.)

Electrophysiologists and industry analysts expect PFA will soon largely supplant radiofrequency ablation and cryoablation because it is safer.

Boston Scientific is also touting *results* from *NEwTON AF*, presented at the AHA meeting as an abstract.

NEwTON AF is a single-arm trial of Boston Scientific's the IntellaNav StablePoint ablation catheter and force-sensing system in subjects with symptomatic, drug refractory, recurrent paroxysmal atrial fibrillation. The trial hit all its safety and efficacy endpoints, with an acute procedural success rate of 98.3%. Nearly 74% of subjects were free from documented atrial-fibrillation recurrence at one year.

Eko's Sensora AI Platform Detects Valve Disease In Real-World Data

Real-world data showed Eko's Sensora digital stethoscope artificial intelligence platform is twice as sensitive to audible signs of valvular heart disease as standard cardiac auscultation with a stethoscope.

The results from 369 patients were presented at the American Heart Association Scientific Sessions on 13 November by Moshe Rancier, from Mass General Brigham Community Physicians in Lawrence, MA. The abstract is also published in *Circulation*.

The study evaluated Eko's digital stethoscope paired with the company's artificial intelligence structural murmur detection algorithm by comparing it to valve-disease detection with an analog stethoscope (auscultation) in the primary care setting.

The company's analysis software is compatible with Eko's Core and Duo stethoscopes to detect atrial fibrillation, and calculate heart rate, QRS duration, and electromechanical activation time. (Also see "*Cardio Catch-Up: Updates From B-Secur, egnite, Vektor, And Other Under-The-Radar Companies*" - Medtech Insight, 20 Jun, 2022.)

In this study, Eko's AI-guided approach was 94.1% sensitive and 84.5% specific. The traditional auscultation method was 41.2% sensitive and 95.5% specific. The AI method identified 22 patients with moderate-to-severe valve disease who were previously undiagnosed and the analog method identified eight previously undiagnosed patients.

The results indicate that the standard method under-detects signals of valve disease, leading to a lower sensitivity when valve disease is present and higher specificity when disease is not present.

"When applied in a primary care setting, a digital stethoscope with structural murmur detection

AI showed meaningful impact on new discovery of valvular heart disease as compared to conventional practice," the investigators concluded. "These results suggest that AI-powered auscultation at the point of care may significantly increase earlier VHD discovery, facilitate appropriate patient care, and improve outcomes."

Abbott-Sponsored Study Shows VAD Patients Can Be Aspirin-Free

Results from the Abbott-sponsored *ARIES HM3* randomized trial showed that advanced heart failure patients implanted with a HeartMate 3 left-ventricular assist device had better outcomes if they did not take aspirin as part of their blood-thinning medication regimen.

Mandeep Mehra of Brigham and Women's Hospital in Boston presented the results at the American Heart Association's Scientific Sessions in Philadelphia on 13 November. The results are also published in *The Journal of the American Medical Association*.

ARIES HM3 randomized 628 patients with a HeartMate 3 to aspirin or placebo. The patients not taking aspirin experienced fewer complications from bleeding and were less likely to be hospitalized compared to the patients who took aspirin daily following their implant surgery.

> *"The data is so compelling that the magnitude of benefit observed in avoiding aspirin is similar to the impact of introducing a new device to the market." – Mandeep Mehra*

The results also showed that the aspirin-free regimen saved money. Over one year, the aspirin-free strategy reduced bleeding-related costs by 41% while not increasing the patients' risk of developing thrombosis.

"The ARIES study moves the needle forward in improving the journey of advanced heart failure patients with a marked improvement in bleeding events, healthcare resource use and cost-savings by a simple decision to avoid the use of aspirin," Mehra said. "The data is so compelling that the magnitude of benefit observed in avoiding aspirin is similar to the impact of introducing a new device to the market."

China Approves J&J's Monarch Robotic-Assisted Bronchoscopy Platform

Johnson & Johnson's Monarch surgery platform and Monarch bronchoscope received regulatory approval in China, making it the first minimally invasive robotic-assisted technology approved for peripheral lung procedures in that country and outside the US.

The system provides bronchoscopic visualization of, and access to, the patient's airways for diagnostic and therapeutic procedures, the company announced on 13 November.

Lung cancer nodules are typically small, deep in the lungs and difficult to reach, confounding early-stage diagnosis and treatment. Monarch can reach small peripheral lung nodules at an earlier stage and with greater precision than traditional surgery, according to the company.

"There are more than two million patients diagnosed with lung cancer each year around the world and nearly 40% of them are in China," said Will Song, president J&J Medtech China. "With this approval, Monarch is poised to aid physicians in China as they work with patients to fight one of the most prevalent and deadly diseases in the country." (Also see "*After Two-Year Delay, J&J Plans To Start Trial Ottava Surgical Robot In 2024*" - Medtech Insight, 7 Nov, 2023.)

The Monarch platform has been used in more than 35,000 cases in the US.