Michigan Outpatient Cardiovascular Association

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EACTS past president puts innovation and inclusivity at the top of the agenda

The immediate past president of the European Association for Cardio-Thoracic Surgery (EACTS) speaks to *Cardiovascular News* about the organization's work to encourage a culture of innovation within the field and to support efforts to improve diversity among the cardiothoracic surgery workforce. Franca Melfi, the first woman President at EACTS, comments that both agendas are closely linked, given their importance in making the specialty attractive to new talent. Both issues featured as priorities within EACTS' five-year strategy, released in March 2024, which sets out the Association's long-term goals to keep pace with the evolving needs of patients and its members.

Melfi is a thoracic surgeon, and it is through her pioneering work in robotic surgery—having performed the first robotic procedure for lung tumour removal in 2001 at University Hospital Pisa (Pisa, Italy)—that she has gained a unique insight into the advent of new technologies in the surgical realm, as well as familiarity with the research and training needs that these novel solutions bring. Melfi drew on this experience during her recent Presidential Address at the EACTS 2024 annual meeting (9–12 October, Lisbon, Portugal), where she told delegates: "Innovation requires courage to challenge established norms and to open doors for new insights, techniques and technology."

"When we talk about innovation, people think of robotic surgery, but in many ways, this is almost the past. I started with robotic surgery almost 23 years ago, at that time it was an unbelievable, unexpected and experimental field," Melfi tells *Cardiovascular News*. Robotic techniques are continuing to advance in the cardiac arena, which she identifies as a fertile ground for innovation, alongside areas such as artificial intelligence (AI) and machine learning, which she says have potential to influence how treatments are delivered.

EACTS' commitment to innovation has included the establishment of an Innovation Hub, launched at the organization's second annual Innovation Summit (19–20 April, Paris, France) this spring, which is intended to attract investment to support the development of cardiothoracic surgical treatments and improve outcomes for patients. Through the Innovation Hub, EACTS members can apply for grant funding to support research and advance innovation in cardiothoracic surgery, with grants to be awarded via a recently established fund through a competitive process over a five-year period. EACTS past president puts innovation and inclusivity at the top of the agenda - Cardiovascular NewS

Abbott launches its largest Navitor Vision valve size in UK

Abbott has introduced a 35mm sized version of its Navitor Vision transcatheter aortic valve implantation (TAVI) system in the UK.
The company has described this the largest valve size, supplied through the smallest delivery system available on the NHS, offering flexibility, accuracy, and stability in a large TAVI valve platform and is being used at King's College Hospital in London.

Offered in a range of valve sizes to treat native annulus diameters, including the smallest TAVI valve size (23mm), the latest iteration of these devices were first introduced to the UK in July 2024.

Alongside the valve size, the platform features a large cell design to preserve coronary access for future interventions, as well as a highly flexible delivery system, with controlled deployment providing clinicians with the opportunity to achieve single-digit pacemaker rates.

King's College Hospital in London, an early adopter of the Navitor TAVI system, is one of the first hospitals to start using the new valve size to treat patients who are at high or extreme surgical risk for open-heart surgery.

Rafal Dworakowski, consultant cardiologist at King's College Hospital, said: "This valve can help improve the way we treat patients, and is an important addition to our range of treatments for heart valve disease." Abbott launches its largest Navitor Vision valve size in UK - Cardiovascular News

AHA 2024: Spironolactone misses primary endpoints in CLEAR SYNERGY trial

Routine use of the blood pressure medication spironolactone among patients who have undergone percutaneous coronary intervention following acute myocardial infarction (MI) may reduce heart failure, but is not likely to reduce mortality, recurrent MI or stroke.
These are among the latest findings of the CLEAR SYNERGY (OASIS 9) trial, presented by Sanjit S Jolly (McMaster University and Hamilton Health Sciences, Hamilton, Canada) at the American Heart Association (AHA) 2024 Scientific Session (16–18 November, Chicago, USA) and

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CLEAR SYNERGY was a randomized, double-blind, 2×2 factorial design, placebo-controlled clinical trial, which randomized 7,062 patients between February 2018 and November 2022 into four groups receiving either spironolactone and the anti-inflammatory medicine colchicine; spironolactone and a placebo; colchicine and a placebo; or two placebos.

Patients were aged an average of 60 years old, and 20% were women. Among them, 95% had ST elevation myocardial infarction (STEMI), and 18% had diabetes type 1 or 2 diabetes.

Jolly presented findings from the analysis of the effect of colchicine within the trial at TCT 2024 (27–30 October, Washington, DC, USA), where he reported that the use of the medication after acute MI did not reduce cardiovascular death, MI, stroke or ischaemia-driven revascularization compared to placebo. AHA 2024: Spironolactone misses primary endpoints in CLEAR SYNERGY trial -

Attention turns to multi-organ denervation as new evidence supports "durability" of blood pressure reductions

New research will investigate the safety and efficacy of multi-organ, hepatic artery and renal artery denervation using the Symplicty Spyral (Medtronic) catheter in uncontrolled hypertension patients who are both on and off medications.
A planned global pilot study, SPYRAL GEMINI, represents the latest frontier in sympathetic denervation research, following the US Food and Drug Administration (FDA) approval of the Symplicity Spyral and Paradise (Recor Medical) renal denervation systems in late 2023. SPYRAL GEMINI will involve only the use of the Symplicity Spyral catheter.

"It is a nice way of saying that the story doesn't stop here with renal denervation. We are exploring other vascular beds for renal denervation therapy, and it so happens that the hepatic artery is highly innervated with sympathetic nerves and would provide a rich target for sympathetic denervation," David Kandzari (Piedmont Heart Institute, Atlanta, USA), who has investigated renal denervation using the Medtronic system, tells *Cardiovascular News*.

"The pre-clinical data would suggest that hepatic denervation combined with renal denervation may not only achieve a potentially greater reduction in blood pressure, but an even more consistent reduction in blood pressure as well."

The study program is anticipated to begin in late 2024/early 2025 and will be "exciting with regard to seeing what the reductions in blood pressure are beyond renal denervation only", according to Kandzari, and whether this may increase the number of individuals with a response from the therapy.

Kandzari recently presented two-year data from the SPYRAL HTN-ON MED clinical trial at TCT 2024 (27–30 October, Washington, DC, USA). The trial investigated the safety and efficacy of renal denervation using the Symplicity Spyral radiofrequency catheter in 337 patients with uncontrolled hypertension prescribed one to three hypertensive drugs Attention turns to multi-organ denervation as new evidence supports "durability" of blood pressure reductions - Cardiovascular News

ACURATE IDE results put spotlight on impact of valve under-expansion after TAVI

"Disappointed is an understatement," Michael Reardon (Houston Methodist DeBakey Heart & Vascular Center, Houston, USA) said of the results of the ACURATE IDE trial comparing the Acurate neo2 (Boston Scientific) transcatheter aortic valve implantation (TAVI) device to two contemporary TAVI systems.
Results of the trial, a prospective, multicentre, randomized study, intended to support regulatory approval for the Acurate platform in the USA, were presented by Reardon at TCT 2024 (27–30 October, Washington, DC, USA). There, Reardon reported that Acurate neo2 failed to meet non-inferiority against two competitor valves—Evolut (Medtronic) or Sapien 3 (Edwards Lifesciences)—across a combined endpoint of all-cause mortality, stroke or rehospitalization at one year.

Investigators have stated that the comparison was "complicated" by a challenging trial environment, with much of the enrolment occurring during the COVID-19 pandemic. Sites were also relatively unexperienced in using the investigational device compared to those used in the control arm, Reardon said, with only 10% of enrolling physicians at the trial's 70 sites throughout the USA having carried out more than 10 cases with Acurate neo2.

"We started this several months before the first COVID-19 wave and it took us 47 months to complete," said Reardon. "The average time between Acurate implants was three months, and only three sites did one a month, so there was not much experience with this valve, while we were continuing to do control valves multiple times every week."

Despite what he described as limited operator experience with the Acurate neo2 platform, Reardon reported that early outcomes with the device were "encouraging", with periprocedural outcomes that appeared in line with those seen in the control arm, no anomalies in echocardiography outcomes such as mean valve gradient and paravalvular regurgitation, and no acute safety signals. However, one-year composite rates of all-cause mortality, stroke or rehospitalization stood at 16.16% in the Acurate neo2 arm and 9.53% in the control arm, meaning that Acurate neo2 did not meet the prespecified 8% margin for non-inferiority ACURATE IDE results put spotlight on impact of valve under-expansion after TAVI - Cardiovascular News

CABG shows benefit over PCI in patients with diabetes and multivessel disease in Swedish registry study

Coronary artery bypass graft (CABG) surgery is associated with significantly lower all-cause and cardiovascular mortality risk and longer median survival time compared to percutaneous coronary intervention (PCI) in patients with diabetes and multivessel coronary artery disease, a new analysis from the SWEDEHEART registry has shown.
These findings were presented by Emma Hansson (University of Gothenburg, Gothenburg, Sweden) as late-breaking science at the European Association of Cardio-Thoracic Surgery (EACTS) 2024 annual meeting (9–12 October, Lisbon, Portugal).

SWEDEHEART is the Swedish national registry recording the outcomes of patients hospitalized for acute coronary syndrome or undergoing coronary or valvular intervention within the country.

Hansson and colleagues used data from the registry, alongside the country's coronary angiography and angioplasty registry and other healthcare registries, with information on hospitalization, drug prescription, socioeconomic status and mortality, to quantify and calculate the mean survival time after CABG or PCI, as well as looking at differences in various sub-populations.

Data were gathered for all revascularizations taking place between 2006–2020, excluding emergency cases, giving a total of 26,166 patients with multivessel disease and diabetes. Of these, 64% underwent PCI and 36% underwent CABG, with data available at a median follow-up of five years. CABG shows benefit over PCI in patients with diabetes and multivessel disease in Swedish registry study

TCT 2024: TRISCEND II reports positive outcomes for tricuspid replacement system

The Evoque (Edwards Lifesciences) tricuspid valve replacement system demonstrated superiority compared to medical therapy alone for the one-year primary endpoint of the TRISCEND II trial.
TRISCEND II is a randomized controlled pivotal trial designed to study the Evoque system with optimal medical therapy (OMT) compared to OMT alone with 2:1 randomization.

The data, presented at the 2024 TCT meeting (27–30 October, Washington, DC, USA), by Susheel Kodali (Columbia University Irving Medical Center, New York, USA) and Suzanne Arnold (University of Missouri-Kansas City, Kansas City, USA) included the full cohort of 400 patients. One-year primary endpoint outcomes have been simultaneously published in *The New England Journal of Medicine*, and one-year quality-of-life (QoL) outcomes in the *Journal of the American College of Cardiology*.
Patients enrolled in the TRISCEND II trial had at least severe tricuspid regurgitation (TR) TCT 2024: TRISCEND II reports positive outcomes for tricuspid replacement system

FYI: Upcoming Dates

- MAHP Conference: July 22nd-25th, 2025
- British Cardiovascular Intervention Society: Jan. 20th-31st, 2025
- January MOCA Meeting, **Date TBD**