Multispecialty Outpatient Cardiovascular Association

March Edition

CRT 2024: Shield system cuts operator exposure to radiation during cath lab procedures

The use of a radiation shield system—Protego (Image Diagnostics)—could markedly cut the exposure of cath lab staff to radiation during coronary and structural heart procedures, new research suggests.

David Rizik (HonorHealth Research Institute, Scottsdale, USA) presented at the 2024 Cardiovascular Research Technologies (CRT) meeting (9–12 March, Washington, DC, USA) the findings of a three-year study investigating the use of the Protego system in 300 cases.

Use of the shield system was compared to 150 cases performed using standard protection, which includes the use of a personal lead apron by operators, as well as a thyroid collar and leaded glasses together with a drop-down shield.

The Protego system consists of a combination of rigid shields above and below the cath lab table, integrated with inter-connecting flexible radiation resistant drapes designed to provide a comprehensive radiation barrier that minimises radiation exposure from the X-ray source, as well as patient scatter. Radiation exposure was measured using real-time dosimetry, which analysed total body exposure at waist and thyroid levels.

Rizik reported that the use of the Protego system reduced operator radiation exposure by >99% compared to standard protection. The median exposure at the waist with Protego was 0.0 (0.0, 0.0) vs 10.0 (5.0, 16.6) mSv, with Standard Protection ($p < 0.001$). The median "head level" radiation exposure measured at the thyroid with Protego was 0.0 (0.0, 0.0) vs 10.0 (5.0, 16.6) mSv with Standard Protection ($p<0.001$). This level of operator radiation exposure with the Protego system is lower than levels ever reported previously with any radiation protection strategy, Rizik noted. CRT 2024: Shield system cuts operator exposure to radiation during cath lab procedures (cardiovascularnews.com)

FYI:

- **EACTS and STS guidelines recognise aorta "as an organ in its own right"**
- **Robotic system "brings transcervical aortic valve replacement a step closer"**

ENVISION trial of Abbott's Navitor TAVI valve in low-risk patients enrolls first patient

Abbott has announced that the first patient has been enrolled in the ENVISION investigational device exemption (IDE) clinical trial.

The global, randomised trial, taking place at 95 sites, will evaluate the safety and effectiveness of Abbott's Navitor transcatheter aortic valve implantation (TAVI) system in approximately 1,500 patients at intermediate or low surgical risk with severe aortic stenosis.

The trial will be used to support expanded indication for the Navitor TAVI system's treatment of aortic stenosis across surgical risk categories. The Navitor Vision valve recently launched in the US and features radiopaque markers that help physicians with implanting the device

Aortic stenosis is one of the most common and life-threatening heart valve diseases. As the world's population continues to age, cases of aortic stenosis are projected to double in the USA in the next few decades, underscoring the need for expanded treatment options, Abbott said in a media release. ENVISION trial of Abbott's Navitor TAVI valve in low-risk patients enrols first patient (cardiovascularnews.com)

BioCardia announces long-term partnership with StemCardia

BioCardia and StemCardia has a long-term partnership to advance StemCardia's investigational pluripotent stem cell product candidate for the treatment of heart failure.

Under the partnership, BioCardia is the exclusive biotherapeutic delivery partner for StemCardia's cell therapy candidate through studies expected to result in US Food and Drug Administration (FDA) approval of an investigational new drug application (IND) and the anticipated Phase I/II clinical development to follow.

"BioCardia has established safe and minimally invasive delivery of cellular medicines directly into the heart," said Chuck Murry, StemCardia's founder and CEO. "Having worked with BioCardia to successfully deliver our bona fide cardiac muscle cells in large animal models of heart failure, we are excited for this partnership to accelerate clinical development and broaden future commercial access to an off-the-shelf heart regeneration treatment."

"StemCardia's team encompasses recognised leaders in the field of cardiac regenerative medicine who are pursuing an elegant strategy to repair the failing heart. We look forward to supporting their efforts with our experienced team and proven, proprietary Helix biotherapeutic delivery system," said BioCardia CEO Peter Altman. "This partnership is expected to enhance future treatment options for millions of people suffering from heart failure

BioCardia announces long-term partnership with StemCard a (cardiovascularnews.com)

MULTISPECIALTY OUTPATIENT CARDIOVASCULAR ASSOCIATION

Settling the paclitaxel versus sirolimus DCB debate

Bernardo Cortese (Fondazione Ricerca e Innovazione Cardiovascolare, Lodi, Italy and DCB Academy) has been among the leaders in research on the use of drug-coated balloons (DCBs) in percutaneous coronary intervention (PCI) across Europe. As the approach continues to gain ground among physicians, new devices using novel coatings such as sirolimus as an alternative to the current standard of care, paclitaxel, have begun to enter the market. Here, Cortese considers the important issues to consider when evaluating these two drugs.

Paclitaxel-coated balloons have been available in Europe since 2007 when the PACCOCATH study came out and since then many technologies with good outcomes have emerged. Sirolimus has taken quite a bit longer, with the first device marketed in 2016—Magic Touch (Concept Medical). From one point of view, sirolimus is more appealing to physicians as limus has won the war against paclitaxel in stents, and those who have come to DCBs relatively recently may hold this view. And, while sirolimus is bringing an important novelty to the field, we have seen a lot of data that paclitaxel works very well.

The drugs are truly different. As paclitaxel stays in the vessel wall for weeks and in some cases months, it can exert some cytotoxic effects in the case of over-dosage. At TCT 2023 (23–26 October, San Francisco, USA) Aloke Finn (University of Maryland School of Medicine, Baltimore, USA) presented data from a study comparing paclitaxel and sirolimus DCBs, showing that the latter was very keen to the vessel wall without any sign of toxicity, whereas the former was associated with some sort of toxicity. We do not understand if this is good or not, but we do know that in 60–70% of cases paclitaxel exerts late lumen enlargement.

When we started to test sirolimus with the Magic Touch DCB in Europe we decided to follow two different strands. One is to compare sirolimus to paclitaxel in a mechanistic study—TRANSFORM I—as well as in clinical studies in a broad population in comparison to stents (TRANSFORM II trial, ongoing). TRANSFORM I compared Magic Touch to Sequent Please (B Braun), which is a well-studied, well-performing paclitaxel-coated balloon. Magic Touch was just outside of the margin for non-inferiority as regards to the angiographic performance of the two devices, and we have speculated a lot about why this may be, with some important items to underline. Settling the paclitaxel versus sirolimus DCB debate - Cardiovascular News

Past, present and future of cardiovascular innovation celebrated at Global Cardiovascular Awards

A founding father of transcatheter aortic valve implantation (TAVI), professor Alain Cribier (University of Rouen, Rouen, France), was posthumously recognised for his role in advancing the field of cardiovascular care at the first Global Cardiovascular Awards.

The awards, hosted by *Cardiovascular News* with support from industry partners Concept Medical, Endologix, Edwards Lifesciences and GE Healthcare, in partnership with the World Heart Federation (WHF), seeks to recognise the innovators and pioneers at the vanguard of efforts to improve the treatment of cardiovascular disease worldwide.

Across 13 categories, awards were presented to some of the individuals, industry leaders and non-profit organisations who are helping to shape the future of cardiovascular care. Each award category was adjudicated by an expert judging panel assembled by *Cardiovascular News*, and the winners were announced at a lavish ceremony at London's Grand Sheraton Hotel yesterday evening (14 March) hosted by the comedian and entertainer Naomi Cooper.

Cribier, the TAVI pioneer whose trailblazing work helped to usher in a new era in interventional cardiology, heralding the advent of the transcatheter treatment of valvular heart disease, sadly passed away in February at the age of 79.

Attendees of the Global Cardiovascular Awards heard moving tributes to Cribier from Michael Reardon (Houston Methodist Hospital, Houston, USA) and Lars Søndergaard the divisional vice president, medical affairs and chief medical officer, Structural Heart at Abbott. Past, present and future of cardiovascular innovation celebrated at Global Cardiovascular Awards (cardiovascularnews.com)

Reminders:

- **Next Board Meeting**: Thursday, April 11th at 12:00pm
- **Next Presentation Volunteer Needed:** Please let Sarah know if available