The CERC Chronicle

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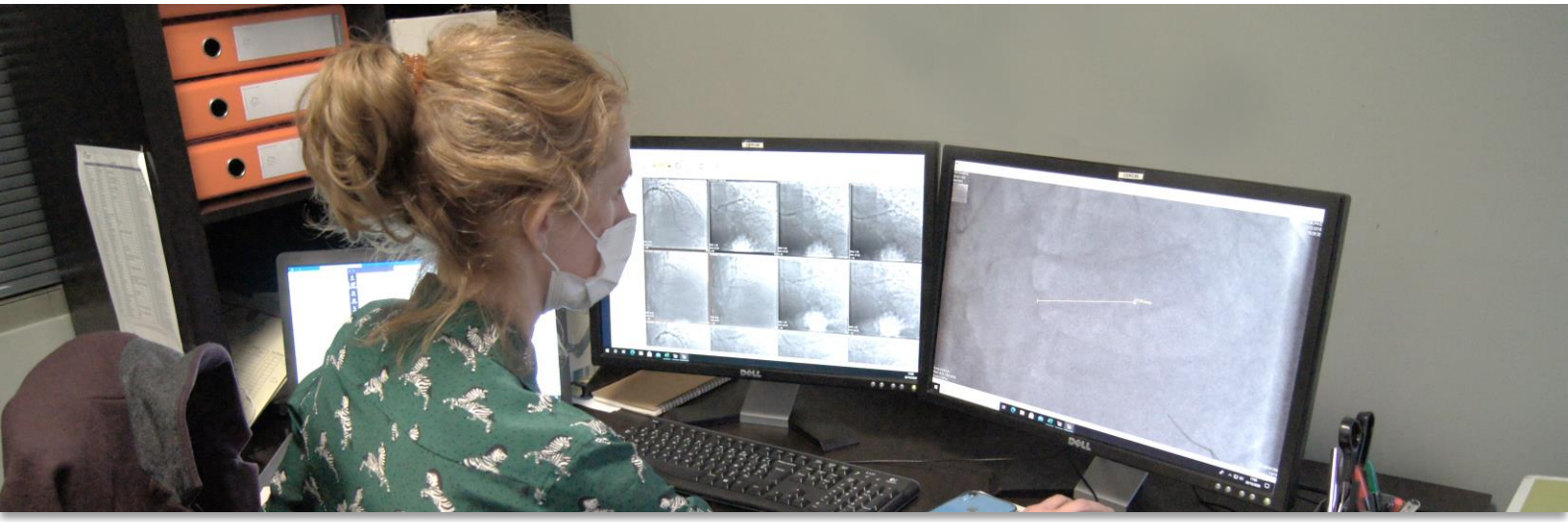


Corelab services at CERC

By Antoinette Neylon,
Corelab Manager

Medical imaging has advanced considerably over the last 40 years since the first angioplasty was performed and now plays an important role in the evaluation of existing and novel therapies. The Corelab at CERC provides expert, centralized and independent analysis of patient imaging data. This data informs the medical community and is used for CE mark approvals and FDA submissions. We work with medical experts across a range of specialties to provide Corelab services for angiographic, CT, Echo, OCT, IVUS and ECG images. Over the years we have analysed imaging data of thousands of patients in multiple clinical trials and registries and our data has been presented at hundreds of international meetings.

No, we don't spend all our time locked in dark rooms looking at screens! We work with our sponsors to determine the type of imaging data and analysis that will best answer their research question. We work with our project managers to develop a corelab package outlining to the clinical investigation sites the process for acquiring and transferring the imaging data and we work with our data managers to develop the CRF so that we have all the data required to answer the research question posed by the sponsor.

All of this could not be achieved without a team. We are especially grateful to Anne Pascale, Aline and Sanga for all their work and interaction with sites. We want to be interactive and available to support the CERC team so if we can help in any way, don't hesitate !!

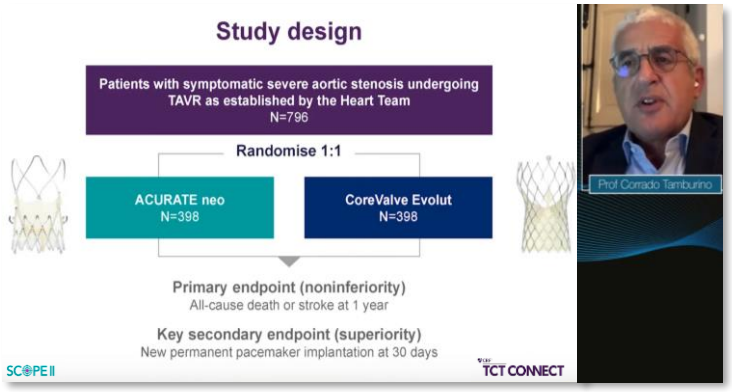
Antoinette Neylon, below at PCR Valves 2020 Opening Ceremony

Inside this issue

SCOPE II presented at TCT Connect and simultaneously published in Circulation

By Davide Capodanno
Director

On October 15, 2020, Corrado Tamburino presented the results of the SCOPE II trial in a late breaking trial session at TCT Connect. SCOPE 2 was a randomized trial managed by CERC performed at 23 centers in 6 countries between April 2017 and April 2019. Patients ≥75 years with an indication for transfemoral TAVR as agreed by the Heart Team were randomly assigned to receive treatment with either the ACURATE neo (n=398) or the CoreValve Evolut bioprostheses (n=398).



The trial is of notable interest for the interventional community because there are few randomized trials in the literature comparing bioprostheses for transcatheter aortic valve replacement, particularly those with supra-annular design. CERC has the legitimate satisfaction of having completed it despite the problems linked to the COVID-19 pandemic. In addition, the trial was published simultaneously with the TCT Connect presentation, in the prestigious journal Circulation (doi.org/10.1161/CIRCULATIONAHA.120.051547).

The primary endpoint of SCOPE II, powered for non-inferiority of the ACURATE neo valve, was all-cause death or stroke at 1 year and occurred in 15.8% of patients in the ACURATE neo group and in 13.9% of patients in the CoreValve Evolut group (absolute risk difference 1.8%, upper one-sided 95% confidence limit 6.1%, p=0.0549 for noninferiority). The key secondary endpoint, powered for superiority of the ACURATE neo valve, was new permanent pacemaker implantation at 30 days and occurred in 10.5% of patients in the ACURATE neo group and 18.0% in the CoreValve Evolut group (absolute risk difference -7.5%, 95% confidence interval -12.4 to -2.60, p=0.0027).

No significant differences were observed in the components of the primary endpoint. Cardiac death at 30 days (2.8% vs. 0.8%, p=0.03) and 1 year (8.4% vs. 3.9%, p=0.01), and moderate or severe aortic regurgitation at 30 days (10% vs. 3%, p=0.002) were significantly increased in the ACURATE neo group and edges of the treated vascular segment.

In summary, transfemoral TAVR with the self-expanding ACURATE neo did not meet non-inferiority compared to the self-expanding CoreValve Evolut in terms of all-cause death or stroke at 1 year, and was associated with a lower incidence of new permanent pacemaker implantation. In secondary analyses, the ACURATE neo was associated with more moderate or severe aortic regurgitation at 30 days and cardiac death at 30 days and 1 year. These results complement those of the prior SCOPE I trial, where the ACURATE neo valve was compared with the balloon expandable Sapien 3 valve. A new iteration of the ACURATE neo valve (ACURATE neo2) has been developed to overcome the current limitations of the device, and possibly improve its clinical outcomes.

ARC App, next step

By Marie-Claude Morice
CEO

CERC is in charge of creating the Academic Research Consortium (ARC) app:
In order to make all ARC initiatives readily available to all physicians who provide in-hospital clinical care, but also to researchers and fellows, the Board recommended the development of an ARC app which would encompass not only ARC HBR but also ARC 2, BARC, VARC… using a single app portal.
The project is to make all the scientific work accomplished under the umbrella of the Academic Research Consortium available in a single app. At the moment, when for example assessing the outcome of patients after TAVI (VARC 2 definitions) or coronary stenting (ARC 2 definitions), each search must be done separately using individual publications in different medical journals: a slow process that is not suitable for use at the bedside.

Dr Antoinette Neylon (CERC) and Dr David Cao (Mount Sinai) are in charge of the scientific content, under the supervision of Dr Roxana Mehran and Marie-Claude Morice and all ARC founders. The plan is to update the ARC HBR first in the next 2 months, then in January 2021 to build the ARC portal, and then every 2 months to make available one initiative on the app (ARC 2, VARC2, etc…).

"e-Visits" for CERC platform

By Laure Morsiani
Clinical Operations Manager

The sanitary crisis that we are presently going through has prevented our CRAs from visiting the investigating centers for several weeks. We have, therefore, been forced to adjust to this new situation and to adopt new working procedures.

Consequently, CERC has developed what we call a "e-Visit". At the centre of this e-Visit, a new highly secure platform for document sharing was specifically customized and has been made available to all investigating centers so that they can upload their non-anonymized research files, such as patient consent forms, medical files or documents involving the training and the responsibilities of the investigating team members that are usually kept on site. CERC's CRAs can access and view these documents, but cannot download, save or print the files.

After reviewing the documents, the CRA schedules a web conference with the investigating team in order to discuss the study advancement status, as well as all pending issues and necessary corrections or any requirements for additional training.

These e-Visits are In compliance with current applicable European regulations, as well as in compliance with FDA regulation.

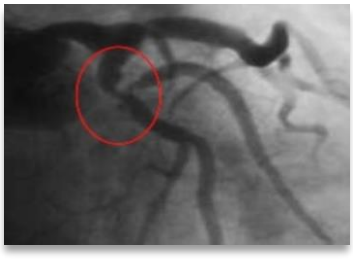
In addition to being able to view/review the centers' files even during a pandemic, we have optimized the numerous advantages associated with the 'e-Visit for CERC' platform, namely the possibility of dividing each visit into several sessions in order to provide training on an 'ad hoc' basis, the possibility of verifying that all necessary documents have been made available to the CRA, the reduction of costs related to physical visits, which is beneficial both for sponsors. In summary, thanks to the new working methods developed by CERC during lockdown, the e-Visits provide the same monitoring quality as traditional on-site visits.

Currently CERC's monitoring strategy is a hybrid strategy encompassing on-site visits and e-Visits because we strongly believe that human interaction is essential for optimal communication and cooperation. The number of on-site visits is calculated according to our risk-based monitoring procedures.

Two new Investigator-initiated trials sponsored by CERIC

KISS *By Bernard Chevalier,*
PI of the trial

While it is generally agreed that side-branch stenting is best avoided when the anatomy is suitable, the optimal technique for dealing with the side-branch during bifurcation PCI remains a matter of debate. Thanks to an unrestricted grant from Medtronic, the KISS study (Keep sIngle Stenting Simple) will evaluate the non-inferiority of no side branch (SB) intervention versus side branch ballooning in the setting of single stenting with systematic proximal optimization technique (POT). The trial is investigator-initiated and run by CERC with a prospective randomized (1:1) design. It will enroll 600 patients in 20 centres from France, Italy, Spain, Portugal, Switzerland and the United Kingdom.



The first patient was enrolled on 9th October 2020 in Hôpital privé Claude Galien by Dr. Champagne. A warm welcome to all investigators!

CAOCT *by Olivier Varenne,*
PI of the trial

Out-of-hospital cardiac arrest (OHCA) is a leading cause of sudden death, and coronary artery disease is observed in up to 70% of such patients. However, detection of significant coronary artery disease in survivors of an OHCA does not necessarily imply a causal link, and identifying the culprit lesion by coronary angiography among patients with non-ST elevation MI (NSTEMI) can also often be challenging .

The CAOCT study is an investigator-initiated trial held thank to a grant from Abbott Vascular and consists of a prospective, multi-centre, single cohort, diagnostic accuracy study. 131 patients, survivors of OHCA will be included in France, Serbia and Belgium. The study aims to compare the angio to the OCT to evaluate the ability to detect the culprit lesion. The trial is undergoing regulatory review.

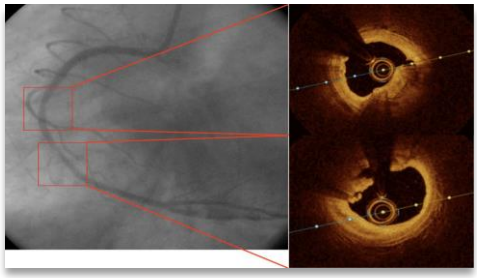


Figure. 55-y-o male after OHCA. ECG showed no ST elevation.
Left panel: non significant lesion is observed in first lesion with more severe distally.
Right panel : Severe atheroma is revealed by OCT without plaque rupture/erosion or thrombus on the first lesion. The distal lesion of the RCA is more severe with plaque rupture and thrombus.

Ability Diabetes Global: the first 100 patients enrolled

By Ute Windhövel
Clinical Operations Manager

The ABILITY Diabetes Global study comparing the ABLUMINUS Sirolimus eluting stent from Concept Medicals to the XIENCE Everolimus Eluting stent from Abbott Vascular in diabetic patients is conducted in transatlantic cooperation between CERC and Icahn School of Medicine at Mount Sinai (NY, USA). Patient inclusion has recently begun, reaching enrollment of the first 100 patients out of a total of 3000 patients in early November.

Latest publications about our trials

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