

The CERC Chronicle

CERC Cardiovascular
European
Research
Center

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EDITORIAL

► CRO Session @ Euro PCR

Once again this year, a selection of trials currently conducted by CERC will be presented during EuroPCR's CRO session on May 19, 2016 from 12:30pm to 1:30pm in Room 343.

Marie-Claude Morice will present two updates of the Leaders Free Trial that will be provided during the hotline session, the first one regarding the ACS population, a pre-defined group of the trial, and the second on the subject of thrombosis versus bleeding benefits.

Horst Sievert will subsequently outline the design and current status of the Strength Trial, a randomized trial comparing simple hydration and the RenalGuard system in patients with severe renal failure undergoing PCI or TAVI.

David Hildick Smith will delineate the status of the new trial initiated by the European Bifurcation Club: EBC Main -one stent versus 2 stents in patients with distal left main lesions.

Bernard Chevalier will present the VIVA trial: CoreValve in degenerated prosthetic valves, whose patient enrolment phase is currently ongoing.

The last presentation will be by **Olivier Varenne**, PI of the Senior Trial: use of Synergy stent with short DAPT in patients older than 75. Patient enrolment for this trial has been completed. The baseline and procedural data are now available.

This session provides an accurate illustration of CERC's mission: To organize and participate in trials which make a difference in the patients' lives.

Marie-Claude Morice



► CERC New Clinical Operations Manager

Laure Morsiani, PhD

Welcome to Laure who joined the CERC Team as Clinical Operations Manager and has a large experience in Interventional Cardiology Clinical Trials.

► CERC New Members are joining us

Philippe Garot, MD

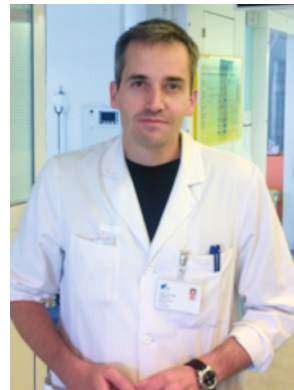
I was eager to join the renowned community of CERC members who lead the way in the field of cardiovascular disease in Europe and beyond.

I strongly believe that learning more about these diseases is the best way to reduce disability and death.

Philippe Garot, MD, Interventional Cardiologist at ICPS Massy France



Stéphane Cook, MD
Why I am joining CERC?



I had the opportunity to start with clinical research in mid 1990s. What a fantastic evolution since then! During my early days, the clinical trials that I was involved with were exploratory, funding was limited and statistics simple. Clinical monitoring was rudimentary and usually made by one single person during off-hours. Endpoints were not systematized. Since then, the advances in the field have been

remarkable: we have moved to transparent funding, electronic reporting using comprehensive databases, powerful statistical tools, reliable analysis, standardized endpoints, and independent adjudication of clinical events.

These advances incorporate each research's finest skills into research "consortia" such as CERC. These now promote unrivaled speed and quality in clinical research, and CERC has fast become a major actor in clinical research in Europe and worldwide. The structure is dynamic and brings together all the necessary skills to make effective clinical research nowadays. It is a privilege to be part of it.

Stéphane Cook is Professor and Head of Cardiology at the University of Fribourg, and Director of the cath-lab at the Fribourg Hospital in Switzerland. His main research interests focus on catheter-based therapies for the treatment of coronary and structural heart disease.

▶ LEADERS FREE @ EuroPCR 2016 ▶ SENIOR Trial

The primary endpoints of the LEADERS FREE trial were presented in a late breaking session at TCT last year and simultaneously published in the New England Journal. The trial demonstrated that for HBR (High Bleeding Risk) patients, a polymer-free Drug Coated Stent (DCS) was both more effective and safer than a BMS when used together with an ultra-short (1 month) DAPT course.

These results have opened new avenues for optimizing treatment of these challenging patients, and a wealth of data are now awaiting further, more detailed, analysis. CERC is thrilled that this process is kicked-off at EuroPCR, where two of the main predefined sub-studies will be presented for the first time in two late-breaking trials sessions.

Christoph Naber will report on 659 patients enrolled in LEADERS FREE who presented with ACS (Main Arena, May 17, 11:20am). Such patients clearly represent a major therapeutic dilemma when they require PCI and also have one or several characteristics that define them as HBR. Their number is rapidly increasing worldwide. The data that will be presented have the potential to impact ACS guidelines in a significant manner.

Philip Urban will address the balance of thrombosis and bleeding in the overall LEADERS FREE population (Théâtre Bordeaux, May 17, 3.30 pm). Specifically, the analysis will focus on the severity & location of bleeding events, the incidence of major thrombotic and bleeding events, and their association with mortality during follow-up. Predictors for both types of complication will be used to assess the risk faced by individual patients.

Philip Urban

▶ CERC is proud to announce

After the successful results of the Leaders free trial, CERC will be in charge of the European part of Leaders free II trial (half of the patients will be recruited in Europe) as well as the CEC activity for the whole study.

Marie-Claude Morice

LEADERS FREE II



Prof. Olivier Varenne
Chief Coordinating Investigator
for Senior Trial

The enrolment of patients in the SENIOR trial has now been completed. Thanks to the strong commitment shown by all the investigators, particularly the French study sites, and by CERC, 1,200 patients over 75 years of age have been included and randomly assigned to treatment with either the latest DES generation (Synergy, Boston) or an equivalent BMS.

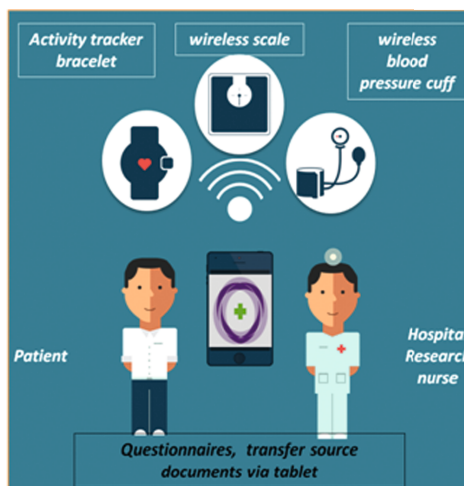
The specificity of the SENIOR study is that the duration of DAPT is determined according to the patients' clinical presentation, regardless of the selected stent. Stable patients are, therefore, prescribed one-month DAPT and unstable patients, including those with STEMI, are prescribed 6-month DAPT, irrespective of the stent used. This represents a marked difference from the LEADERS FREE trial where all patients received 1-month DAPT.

The SENIOR population is composed of patients at high risk of ischemia and bleeding. In addition, many patients are on oral anticoagulant medication due to the presence of atrial fibrillation or for other reasons.

The primary endpoint has been conventionally defined as the occurrence of MACCE at 12 months and should be presented during the ESC 2017.

▶ UP SMART Follow-up

CERC provides a new connected tool for patient follow-up:



► CERC Corelab Experts



Anne-Pascale Giraud
CERC Corelab Coordinator
& QCA Angio Analyses



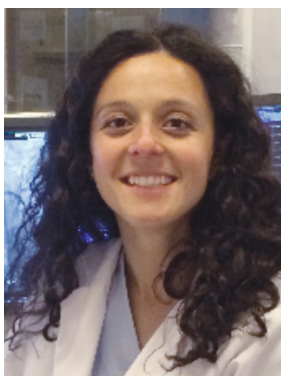
Jérôme Garot, MD
Cardiologist, Head of the Cardiovascular MRI Department, ICPS, Massy since 2008. NUCLEUS Member of the Working Group on Cardiovascular MR of the European Society of Cardiology and member of the Working Group on Echocardiography of the European Society of Cardiology. Corelab MRI reviewer.



Thomas Hovasse, MD
Cardiology Department, ICPS, performing cardiac CT since 2004. Special fields of interest are clinical research, cardiovascular imaging, PCI, TAVI, mitral repair. Tutoring in cardiac CT, valve planning, corelab for TAVI and mitral analysis.



Mathieu Poupineau, MD
Cardiologist
Head of the ICCU, ICPS, Hôpital Privé Claude Galien, Quincy, France
Echocardiographer, Corelab
Specialist for CERC since 2009.



Francesca Sanguineti, MD
Interventional Cardiologist
Cardiac MRI and ICCU at Hospital Simone Veil - Paris ECG Corelab
Specialist, MRI corelab specialist.



Ivana Stankovic, MD
currently working in the cardiology department non-invasive diagnostic unit in the Clinical Center of Belgrade, Serbia. Previously, she was part of independent core lab, CorExpert, Belgrade.




Zlatko Mehmedbegovic, MD
interventional cardiologist, Department of cardiology, Clinical Center of Serbia. Special fields of interests are clinical research, study coordination, project management, cardiovascular imaging, bifurcation PCI. Also, previously, appointed as member of QCA core lab, CorExpert. Member of WGIC of Cardiology Society of Serbia. Angio, IVUS and OCT corelab expert for CERC.



Dragan Topic, MD employed as interventional cardiologist in ICVD "Dedinje", Belgrade, Serbia. Special fields of interest CTO, complex PCI, study adjudication, intravascular imaging. Member of WGIC of Cardiology Society of Serbia. Also, previously, appointed as member of QCA core lab, CorExpert, angio corelab expert.

Bernard Chevalier



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