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The CERC Chronicle

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EDITORIAL

CERC's 10th Anniversary

CERC was founded in 2008 by a group of interventional cardiologists who firmly believed in the need for establishing a new CRO dedicated to Cardiology to enhance the quality and increase the numbers of clinical studies initiated in Europe. Our self-assigned mission, supported by our industrial and pharmaceutical partners, was to design groundbreaking clinical studies with the purpose of redefining medical practice in order to improve our patients' outcomes.

The international, multicultural team that we have been gradually building at CERC is composed of high level scientists from various backgrounds (15 languages are currently spoken at CERC) who have enabled us to become a highly reputable clinical research organization.

We are very proud to have achieved our initial objective of successfully carrying out clinical trials with the invaluable involvement of physicians and medical device companies.

We have been instrumental in helping many centers to undertake clinical research studies for the first time and we have guided them throughout their journey to becoming very efficient investigating centers. Other renowned cardiologists have joined CERC's founding group and their experience and expertise have enriched CERC's strategies (see opposite column).

CERC has already conducted numerous major studies and is currently coordinating many more.
We are extremely grateful to all our sponsors for the trust they have placed in us, to the physicians who have contacted us with innovative ideas for original studies, to the investigators and study coordinators who have been tirelessly enrolling patients, to our teams in CERC, CERC Asia and CERC Deutschland who strive daily to bring these studies to fruition, to the CEC and DSMB members who have offered their knowledge and their thoroughness, and finally, to the CERC's founders who relentlessly contribute to enhancing clinical research achievements and improving patient care, thus allowing us to envision a promising future.

Marie-Claude Morice
CEO

euroPCR

COME AND VISIT US
BOOTH M6
LEVEL 2

Final Outcomes of all trials managed by CERC

The vast majority of CERC trials had a positive outcome.

A word from a CERC Board Member

I'm really excited to be a part of CERC and grateful to the founding members and to the CERC board for giving me this privilege and opportunity. I already knew CERC as an established and trusted European platform for conducting clinical trials according to the highest quality standards.

I was also impressed by the ability of this group to come up with thoughtful study designs that make the trials not only feasible but also impactful, and by the ability to look at the future evolution and development of research in interventional cardiology. From the inside, I can now appreciate the enthusiasm and professionalism of all the people involved: the great results achieved in the last years come as no surprise. I will do my best to contribute actively and I trust I will learn a lot from this experience.

Davide Capodanno

SELECTED CURRENT TRIALS AT CERC

The SENIOR trial at the EuroPCR 2018: What's new?

The Senior study is an international randomized trial comparing two types of stents, namely a drug-eluting stent (Synergy) and a bare metal stent (Rebel), in patients over 75 years of age deemed eligible for PCI. The duration of double antiplatelet treatment (DAPT) was determined prior to randomization, according to the patients' clinical presentation (6 months in unstable patients, 1 month in stable patients).
The results of the primary endpoint analysis at one year (all-cause mortality, stroke, MI, Id TLR) were presented during the LBT session of the latest TCT and published simultaneously in The Lancet.
Several sub-group analyses will be presented at the forthcoming EUROPCR congress.
First, **patients who received one-month DAPT**.
Which patients received 1-month DAPT in both groups? What is the percentage of patients with stable angina? What are the MACCE rates in DES vs. BMS? Do the benefits observed in the overall study patients who received a DES (namely, less MACCE, less revascularization, similar bleeding rate) extend to this subgroup as well?
A poster presentation will detail the differences between the recipients of **one-month DAPT** and those **who received 6-month DAPT**.
The outcome of the **subgroup of patients with ACS** will also be reported, they represent half of the patients.
Finally, the analysis of a subgroup **of patients with atrial fibrillation** is eagerly awaited as this subset raises challenging issues in clinical practice. Indeed, the antithrombotic treatment administered to these patients is complex, given their exposure to bleeding risks associated with triple anti-thrombotic therapy. There were 211 such patients in the Senior trial (17.6%). The selected and effective DAPT durations as well as MACCE and bleeding rates will be reported.

Olivier Varenne on behalf of the Senior Trial Investigators

Boston Scientific

Ceric Center for European Research Initiatives in Cardiovascular Medicine

Enlight KHK Registry

GERMANY

We are delighted to announce that the first registry entrusted to CERC Deutschland, initiated and conducted solely in Germany, will start in June this year. We will conduct the Enlight KHK Registry in collaboration with 6 German hospitals, two health insurance companies and the Institute for Health Economics and Clinical Epidemiology of Cologne University. Its aims include the analysis of the current diagnosis process and appropriateness of indications as well as the nature and extent of possible deviations from the current guidelines in patients with coronary heart disease. Enlight KHK is financed by a grant from the Innovation Committee of the *Gemeinsamer Bundesausschuss*.

Ute Windhövel
CEO CERC Deutschland

BioFreedom STEMI Registry in Asia

ASIA

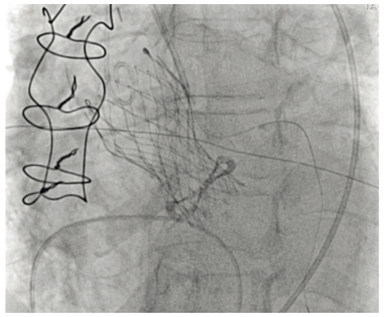
I am most excited to partner CERC Asia to get the Biofreedom STEMI registry. STEMI FREE would provide a great opportunity to investigate the STEMI population in Asia in a scientifically robust manner. The use of Biofreedom stent in Primary Angioplasty should be the logical next step to explore the unique Biolimus property in ACS patients and how the polymer free stent perform in "unknown bleeding risk" ACS subjects.
I am looking forward to working closely with like minded investigators across Asia to run the study. The chance to make new friends and explore budding trial sites will be equally rewarding.
I am very grateful for placing the trust in me. I am confident that with the expertise and support from CERC Asia we can deliver a well conducted study with robust clinical data.
This is the beginning of a beautiful partnership in Asia.

Paul Ong
Principal Investigator of the BioFreedom Stemi Registry

BIOSENSORS INTERNATIONAL

VIVA Trial

The VIVA trial, sponsored by Medtronic, is the first study to evaluate the **self-expanding Corevalve in failed** bioprostheses. One-year follow-up is now being collected and these results will be presented at the next **PCR London Valves**.



Bernard Chevalier
General Director

Medtronic

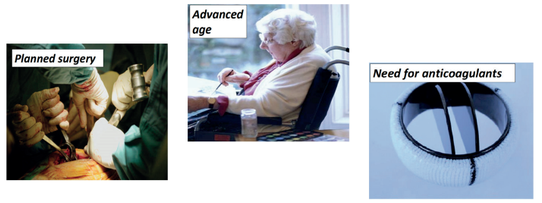
The CERC Chronicle

High Bleeding Risk patients (HBR) Definition by the ARC

ARC HBR

High Bleeding Risk (HBR) patients are clearly a very heterogeneous group, and while several randomised trials are currently actively recruiting HBR patients, there is no definite agreement on exactly who these patients are, and how their bleeding risk can be more precisely assessed. The problem is further compounded by the delicate balance of bleeding and thrombotic risks, since they both should be taken into account when deciding on the optimal type, intensity and duration of antithrombotic treatment after PCI.

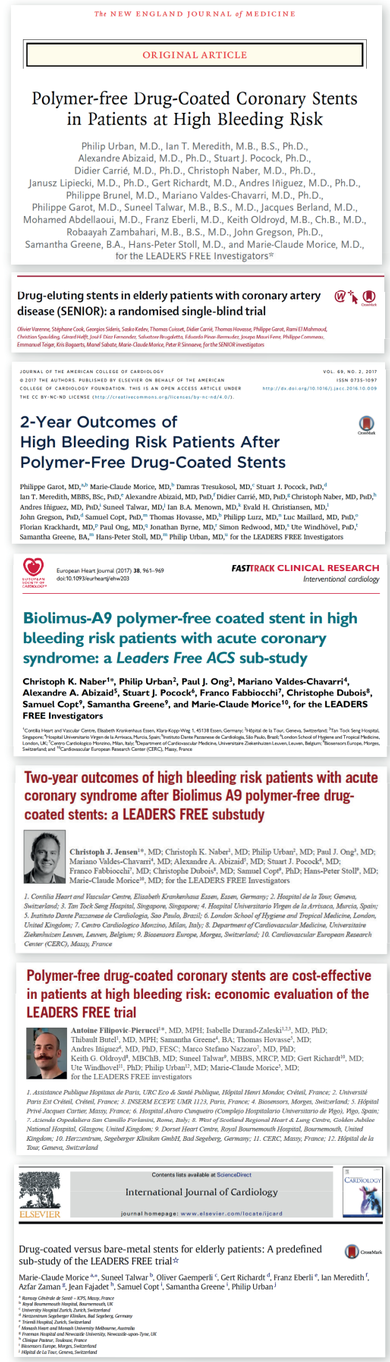
CERC is therefore proud to announce that it is in charge of organising a new ARC Focus Group that will work on a definition of HBR patients. The group will comprise 30 internationally recognised experts, be sponsored by 22 industry partners, and hold two working meeting in 2018 (chairs Philip Urban, Roxana Mehran, Marie-Claude Morice and Mitchell Krucoff).



The ARC group has an exceptional track record in producing several seminal papers that have defined clinical events that are of critical importance both to clinicians in everyday practice and to investigators who either design trials or need to compare and/or combine results from different trials. Stent thrombosis, bleeding after PCI ("BARC") or events after TAVI ("VARC") are among the main ARC efforts that have durably impacted interventional cardiology.

Philip Urban
Associate Director

Publications of studies on HBR patients managed by CERC



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Polymer-free Drug-Coated Coronary Stents in Patients at High Bleeding Risk

Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial

2-Year Outcomes of High Bleeding Risk Patients After Polymer-Free Drug-Coated Stents

FASTTRACK CLINICAL RESEARCH
Interventional cardiology

Biolimus-A9 polymer-free coated stent in high bleeding risk patients with acute coronary syndrome: a *Leaders Free ACS* sub-study

Two-year outcomes of high bleeding risk patients with acute coronary syndrome after Biolimus A9 polymer-free drug-coated stents: a LEADERS FREE substudy

Polymer-free drug-coated coronary stents are cost-effective in patients at high bleeding risk: economic evaluation of the LEADERS FREE trial

International Journal of Cardiology

Drug-coated versus bare-metal stents for elderly patients: A predefined sub-study of the LEADERS FREE trial☆