The CERC Chronicle

Issue No. 16 – May 2020

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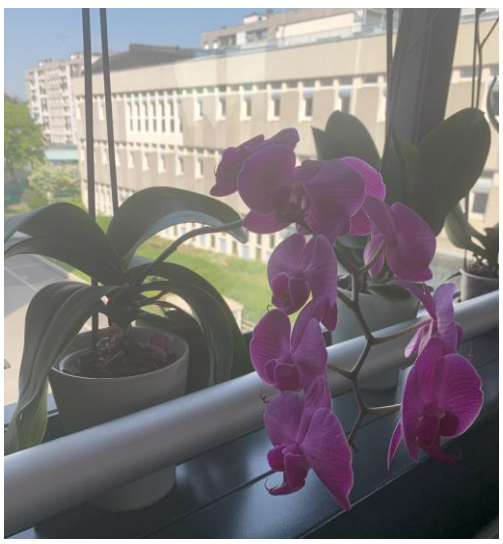


CERC is over 50

The coronavirus outbreak started shortly after the number of CERC's employees reached 50...

During this period, CERC's team was mostly working from home in optimal conditions given that home office has been in place for quite some time in our company. Our open workspace was empty and our lovely orchids were thirsty!

Despite the current situation we are continuing our activities. We enquire after and keep in touch with hundreds of investigating sites where enrolment and follow-up are ongoing.

We are striving to adjust the necessary follow-up of patients to the very disruptive circumstances they are going through. In addition to comforting them, we consider it our duty to try to keep in touch with all the patients who have agreed to take part in research trials.

Regulatory submissions, corelab, data management and statistical analysis are being carried out as usual and all our sponsors are kept informed regularly of the studies' advancement status.

Like everyone else, we are to find all of our teams back together at CERC. Personally speaking, I am impatient to see our office space brimming with life and energy again.

EuroPCR which is such an outstanding forum of shared competencies and intelligence was not held this year... We can't wait till next year's edition!

Marie-Claude Morice
CEO

ABILITY Diabetes Global: a major cooperation with our US partners

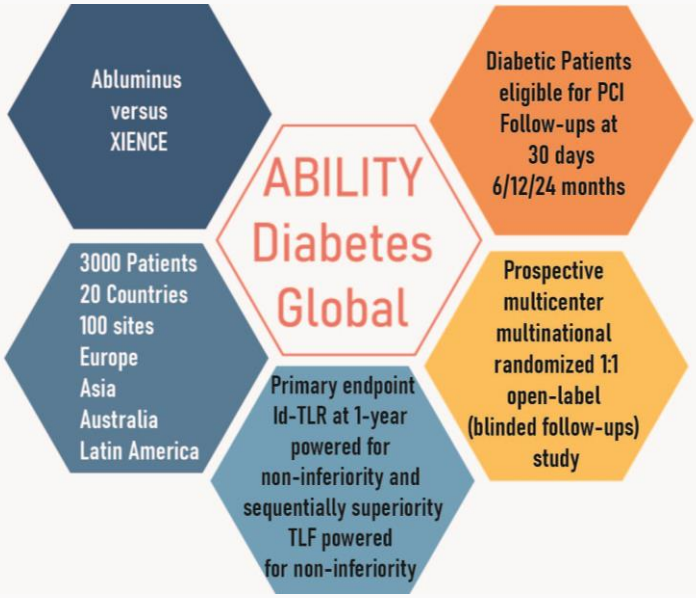
By Philippe Garot
Director

Manish Doshi
Concept Medical

CERC is happy to announce that Concept Medical have entrusted CERC (Massy, France) and Icahn School of Medicine at Mount Sinai (NYC, USA) with the overall management of a large international trial that will assess the efficacy and safety of the ABLUMINUS Sirolimus-eluting DES+ in diabetic patients by comparing it to the Xience EES: ABILITY Diabetes Global.

Roxana Merhan
Mount Sinai

This transatlantic cooperation is a first for CERC, and we are thrilled to be working with Roxana Mehran, Director of Interventional Cardiovascular Research and Clinical Trials at Mount Sinai, and her team. The trial addresses a true unmet need of PCI, sincediabetic patients continue to suffer high event rates after coronary stenting, even with the best of current second-generation DES. The design of the ABLUMINUS stent has very significant potential to impact the restenosis process in high risk patients, since the sirolimus and biodegradable polymer coating is applied simultaneously to the stent and delivery balloon, thus producing a combined "DES + DEB" in a single device, allowing for the delivery of a very homogeneous drug dose along the entire length and edges of the treated vascular segment.



With three world-class PIs (Antonio Colombo, Shigeru Saito and Alexandre Abizaid), the size of the trial (3000 patients) will allow for a non-inferiority analysis for the main endpoints of clinically-driven TLR and TLF, with a sequential superiority analysis for cd-TLR. While it is planned to enroll patients from over 100 sites in Europe, Asia, Latin America and Australia, the trial design has been discussed with the FDA, since the results are intended to be part of a submission package for US approval.

Antonio Colombo

Shigeru Saito

Alexandre Abizaid

MASTERDAPT, recruitment completed!

By Philip Urban
Director

CERC is proud to announce that the recruitment of 4,300 patients in the MASTER-DAPT study was achieved before the end of last year!

Aris Moschovitis

The MASTER DAPT study (clinicaltrial. govNCT03023020) is the first randomized controlled trial aiming at ascertaining the optimal duration of antiplatelet therapy in HBR patients treated with Sirolimus-eluting bioresorbable polymer-coated stent implantation Terumo).

This investigator-initiated study compares an abbreviated versus a prolonged duration of antiplatelet therapy after bioresorbable polymer-coated SES implantation (Ultimaster Tansei, Terumo, Tokyo, Japan) in 137 interventional cardiology centers. MASTER DAPT is powered to assess the non-inferiority of the abbreviated regimen with respect to the net adverse clinical and MACCE composite endpoint and the superiority in terms of major and clinically relevant bleedings.

Patients from 3 continents (Europe, Asia, Oceania) have been enrolled in the study and the three best country-recruiters were the Netherlands, France and Switzerland. In addition, 5 sites reached the 100th patient's milestone including Bern (CH) Dr. Aris Moschovitis having randomized more than 350 patients in the trial!

The results of the MASTER DAPT study are planned to be presented at the EuroPCR Meeting in 2021.

KISS : another bifurcation trial

By Bernard Chevalier

Recent studies have proven the benefit of single stenting in the treatment of bifurcation lesions. However, the debate is still ongoing about the added value of SB interventions in the setting of a provisional stenting approach when conducted according to European Bifurcation Club (EBC) recommendations, namely with systematic use of proximal optimization technique (POT) in order to adjust stent deployment to the two diameters of the main vessel as established by the fractal nature of coronary tree. Studies evaluating the potential benefit of kissing balloon have been conducted before the systematic use of POT.

In the treatment of bifurcation lesions, the KISS (Keep sIngle Stenting Simple) study will evaluate the non-inferiority of no side branch (SB) intervention versus side branch ballooning (with or without kissing balloon inflation), in the setting of single stenting with systematic proximal optimization technique (POT). Patients will be randomized after main vessel stenting and POT if the SB is patent with a normal flow and no signs of ischemia.

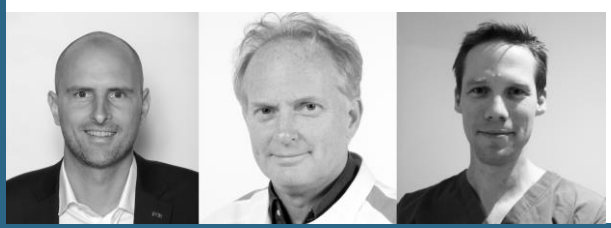
Ceric
Center for European Research Initiatives in Cardiovascular Medicine

The KISS study is an investigator-initiated, CERIC sponsored, multi-centre, prospective, randomized (1:1) non-inferiority trial aiming to compare these two bifurcation PCI strategies, performed in 6 European countries where Medtronic Resolute Onyx stent is CE approved.

Five hundred ninety-six consecutive patients are planned to be enrolled in up to 20 participating investigational sites. The primary endpoint will evaluate the rate of peri-procedural MI using the ARC-2 definition and secondary analyses will include clinical endpoints @ 1-year follow-up. Regulatory approval is ongoing.

Welcome to cerc 3 new members

It's a great pleasure to announce that CERC board has welcomed 3 brilliant new members (left to right below): Drs Thomas Cuisset, Peter Smits and Darren Mylotte. Their arrival will enhance even more CERC's global reach.
A warm welcome to them!



The ARC-HBR initiative – Part 2

By Davide Capodanno
Director

Investigating the risk balance of thrombotic and bleeding events after percutaneous coronary intervention (PCI) is especially relevant for patients at high bleeding risk (HBR). In 2019, the Academic Research Consortium for HBR (ARC-HBR) proposed a consensus definition of HBR in an effort to standardize the patient population involved. CERC organized the meetings of the ARC-HBR group. This finally led to the presentation of the consensus document at EuroPCR 2019 and to the simultaneous publication in Circulation and the European Heart Journal.

The second initiative from the ARC-HBR is to produce a second consensus document and thus propose recommendations to guide the design of clinical trials of devices and drugs in HBR patients undergoing PCI. Two meetings of the ARC-HBR group took place in Washington, DC, USA, in April 2019, and Paris, France, in October 2019, once again organized by CERC and attended by the same experts from Europe, the USA and Asia, as well as representatives from the US FDA, the Japanese PMDA, a European Notified Body (DEKRA Certification BV, Arnhem, the Netherlands), and observers from the cardiovascular device and pharmaceutical industries. The output of the meetings will be published soon. The authors hope that this second document will promote consistency in trial design across a potential spectrum of applications in HBR patients, including evaluation of novel technologies and iterations of existing devices. This context is particularly important for the ARC-HBR definitions, which are intended for use in patients who have historically been under-represented in device and drug studies, and for whom there is a need for further understanding of both device and drug benefit/risk.

ARC HBR meeting in Guermantes, October 2019

Last publications about our trials

Circulation: Cardiovascular Interventions

ORIGINAL ARTICLE

Global Approach to High Bleeding Risk Patients With Polymer-Free Drug-Coated Coronary Stents

The LF II Study

Mitchell W. Krucoff, MD; Philip Urban, MD; Jean-François Tanguay, MD; Thomas McAndrew, PhD; Yiran Zhang, MS; Sunil V. Rao, MD; Marie-Claude Morice, MD; Matthew J. Price, MD; David J. Cohen, MD; Mohamed Abdel-Wahab, MD; Shamir R. Mehta, MD; Benjamin Faurie, MD; Brent McLaurin, MD; Corie Diaz, MBA; Hans-Peter Stoll, MD; Stuart Pocock, MD; Martin B. Leon, MD

AHJ American Heart Journal

Design and rationale of the Management of High Bleeding Risk Patients Post Bioresorbable Polymer Coated Stent Implantation With an Abbreviated Versus Standard DAPT Regimen (MASTER DAPT) Study

Enrico Frigoli, MD,[a] Pieter Smits, MD,[b] Pascal Vranckx, MD, PhD,[c] Yokio Ozaki, MD, PhD,[d] Jan Tijssen, MD, PhD,[e] Peter Jüni, MD,[f] Marie-Claude Morice, MD,[g] Yoshinobu Onuma, MD, PhD,[h] Stephan Windecker, MD,[i] André Frenk, PhD,[i] Christian Spaulding, MD,[j] Bernard Chevalier, MD,[k] Emanuele Barbato, MD, PhD,[l,m] Pim Tonino, MD,[n] David Hildick-Smith, MD,[o] Marco Roffi, MD,[p] Ran Kornowski, MD,[q] Carl Schultz, MD, PhD,[r] Maciej Lesiak, MD, PhD,[s] Andrés Iñiguez, MD, PhD,[t] Antonio Colombo, MD,[u] Mirvat Alasnag, MD,[v] Ajit Mullasari, MD,[w] Stefan James, MD, PhD,[x] Goran Stankovic, MD, PhD,[y] Paul J. L Ong, MD,[z] Alfredo E Rodriguez, MD, PhD,[aa] Felix Mahfoud, MD,[ab] Jozef Bartunek, MD, PhD,[l] Aris Moschovitis, MD,[i] Peep Laanmets, MD,[ac] Sergio Leonardi, MD,[ad] Dik Heg, PhD,[a] Mikael Sunnåker, PhD,[a] and Marco Valgimigli, MD, PhD[i] *Bern, Geneva, Switzerland; Rotterdam, Amsterdam, Eindhoven, the Netherlands; Hasselt, Aalst, Belgium; Aichi, Japan; Ontario, Canada; Massy, Paris, France; Naples, Italy; Brighton, United Kingdom; Tel Aviv, Israel; Perth, Australia; Poznan, Poland; Vigo, Spain; Milan, Pavia, Italy; Jeddah, Saudi Arabia; Chennai, India; Uppsala, Sweden; Belgrade, Serbia; Singapore, Singapore; Buenos Aires, Argentina; Homburg, Germany and Tallinn, Estonia*

CRM

Absorb Bioresorbable Scaffold Versus Xience Metallic Stent for Prevention of Restenosis Following Percutaneous Coronary Intervention in Patients at High Risk of Restenosis: Rationale and Design of the COMPARE ABSORB Trial

Chun Chin Chang [a,b], Yoshinobu Onuma [a,c], Stephan Achenbach [d], Emanuele Barbato [e], Bernard Chevalier [f], Stéphane Cook [g], Dariusz Dudek [h], Javier Escaned [i], Tommaso Gori [j], Viktor Kočka [k], Giuseppe Tarantini [l], Nick E.J. West [m], Marie-Claude Morice [n], Jan G.P. Tijssen [o], Robert-Jan van Geuns [a,p], Pieter C. Smits [q,*], on behalf of theCOMPARE ABSORB trial investigators

ORIGINAL STUDIES

Catheterization & Cardiovascular Interventions

Prospective evaluation of drug eluting self-apposing stent for the treatment of unprotected left main coronary artery disease: 1-year results of the TRUNC study

Carlo Briguori MD, PhD[1] | Corrado Tamburino MD, PhD[2] | Gillian A. J. Jessurun MD, PhD[3] | Markus Meyer-Geßner MD[4] | Krzysztof Reczuch MD, PhD[5,6] | Bernardo Cortese MD[7] | Luc Maillard MD, PhD[8] | Rutger L. Anthonio MD, PhD[3] | Alessio La Manna MD[2] | Marie-Claude Morice MD[9] | David Bouchez MSc[10] | Anaïs Balland MSc[10] | Vi-Phong Huynh MSc[10] | Andreas Baumbach MD[11]

JACC Cardiovascular Interventions

Left Ventricular Rapid Pacing Via the Valve Delivery Guidewire in Transcatheter Aortic Valve Replacement

Benjamin Faurie, MD,[a,b] Géraud Souteyrand, MD,[c] Patrick Staat, MD,[b] Matthieu Godin, MD,[d] Christophe Caussin, MD,[e] Eric Van Belle, MD, PhD,[f] Lionel Mangin, MD,[g] Pierre Meyer, MD,[h] Nicolas Dumonteil, MD,[i] Mohamed Abdellaoui, MD,[a,b] Jacques Monségu, MD,[a,b] Isabelle Durand-Zaleski, MD, PhD,[j] Thierry Lefèvre, MD,[k] for the EASY TAVI Investigators

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