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The CERC Chronicle

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EDITORIAL

Presentation of CERC ASIA

CERC is proud to announce the opening of CERC ASIA in Singapore in January 2017. We decided to set up the first CERC branch in Asia, as we are convinced that this part of the world is bound to play a major role in the near future.
CERC is already involved in worldwide trials with study sites in Asia, and our presence in Singapore will allow us to strengthen our relationship with them. Furthermore, our objective is to share our ethos and expertise in order to support the development of Asian clinical research.

Marie-Claude Morice
CEO

Rosa D'Alessio
is in charge of CERC Asia.
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CERC in Figures

CERC New Members

Felix Mahfoud, *MD*

Why I am joining CERC?

Despite the significant progress made in the field of cardiovascular medicine in the last couple of years, many research questions remain unanswered. New devices and treatment concepts are being developed and need to be scientifically investigated to understand their true impact for patient care. I really enjoy designing, conducting, executing, and participating in clinical trials to enhance our knowledge. I am truly proud and honored to join a group of distinguished experts in clinical research at CERC.

Felix Mahfoud is Associate Professor and Senior Physician of Internal Medicine and Cardiology at Saarland University Hospital and Affiliate/Visiting Professor of the Harvard-MIT, Biomedical Engineering, Boston.

His specific scientific interests include patho-physiology, conservative and novel interventional therapies of heart failure, and hypertension.

THREE CERC TRIALS

Oppose

David Hildick-Smith presented the OPPOSE registry at TCT 2016 (100 patients treated with the Occlutech Figulla Flex PFO closure device)

1/ Given what we know today, what are your own current indications for closing a PFO in routine clinical practice?

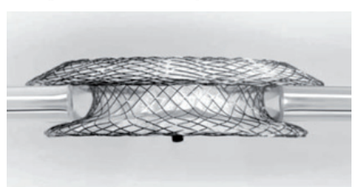
In the UK NHS England has recently stopped funding PFO closure procedures. It's a bizarre situation because they have been funded for 20 years but now that the evidence of benefit is at its strongest, and the FDA have approved PFO closure, NHS England has called time on it instead! Be that as it may, patients with cryptogenic stroke, decompression sickness, and orthodeoxia platypnoea syndrome are all good candidates for PFO closure. For the cryptogenic stroke patients if they have a resting shunt, a floppy interatrial septum, a history of Valsalva or a history of immobilisation prior to the stroke, these are all factors which favour interventional treatment.

2/ How often can it be an outpatient procedure?

PFO closure can be done on a Day-Case basis in nearly all situations. The procedure itself is low-risk and takes about 30 minutes. Pre-procedural TOE is very helpful but if this isn't available then intracardiac echo can be used instead very successfully and means that patients only need light sedation, or sometimes none at all.

3/ What are the main features of the OPPOSE registry?

The main feature I wanted for the OPPOSE Registry was first class scrutiny of the study itself. Many PFO Registries have reported "closure rates" in a self-reported and unmonitored way and therefore are of limited value. Few PFO studies have had rigorous external monitoring of the study and CoreLab adjudication of the echos. I wanted the study to be robust in that way and therefore produce results which would withstand proper scientific scrutiny, and I think we achieved that.



Occlutech®

COMPARE ABSORB

COMPARE-ABSORB, an investigator-initiated randomized trial, coordinated by Peter Smits (PI; Maasstad Ziekenhuis, Rotterdam) and Robert-Jan Van Geuns (Co-PI, Erasmus, Rotterdam) and sponsored by CERIC. We are happy to announce that enrollment is going well and has now exceeded 60% of the planned 2100 patients.

Patients with complex lesions (diabetes, multivessel targets, long or totally occluded target lesion, bifurcation lesion with single stent strategy) are the focus of this comparative study of the Absorb BRS versus Xience, an everolimus-eluting metallic DES. This is the first trial aimed at this specific population with the ambition to systematically apply up-to-date sizing and deployment strategies of bioresorbable scaffold ("PSP").

Peter Smits

Recent published data with this platform emphasize the major potential impact of this large and unique study. In fall, the annex inDES restenosis cohort has started enrollment to assess the role of Absorb in this indication.

Full enrollment of COMPARE-ABSORB is expected in April/May 2017. One-year follow up will be necessary to evaluate the first part of the co-primary endpoint: the clinical non-inferiority versus DES. The second part of the primary evaluation will be a late landmark superiority analysis between 1 and 5 years.

Robert-Jan Van Geuns

The CERC Chronicle

Scope II – Interview with Prof. Tamburino

Prof. Tamburino (Ferrarotto Hospital, University of Catania) is the PI of the SCOPE II trial along with Prof. Christian Hengstenberg (Deutsches Herzzentrum, Munich) as co-PI.

1/ Can you tell us about the specific features of the Symetis Acurate neo valve?

The acurate neo bioprosthesis is the transfemoral version of this second-generation TAVI device, a self-expandable valve with a unique combination of several key features: supra-annular porcine pericardium leaflets, supra-annular anchoring crown, minimal left ventricle protrusion with inner and outer pericardium skirts. The top-down deployment of the valve allows a stable, precise and well tolerated positioning of the frame.

2/ What are the key points of SCOPE II trial?

This a head-to-head comparison versus the Corevalve Evolut R in a typical European population of patients treated with TAVI. The study is an investigator-initiated trial under the sponsorship of CERIC. We aim to show non inferiority at one year for a combined endpoint of all-cause mortality and/or stroke and superiority in terms of the 30 day requirement for a new pacemaker implantation. The study will enroll 764 patients by centers across Europe.

3/ How clinically important are head-to-head comparative studies?

Scope II will be one of the first to achieve this goal in Europe. Initial prospective studies using this platform have shown a high safety/efficacy profile with low rates of paravalvular leak and pacemaker implantation. Many devices are gradually becoming available and high quality comparative data are mandatory to guide physician in their daily practice choice. This is of particular importance in the light of extending TAVI indication in intermediate and low risk patients.

CERC – Clinical Monitoring Team

Do you know CERC's CRAs team?

From left to right, **Hatim**: visiting sites in Italy, UK, Ireland, France and Switzerland ; **Aziz**: visiting sites in France and UK, **Shalini**: visiting sites in France and UK, **Hella**: CRA Manager, **Chloé**: visiting sites in France, Spain and UK, **Pauline**: visiting sites in Germany, Denmark, Austria and Switzerland, **Mallik**: visiting sites in France, in the Netherlands and in the Middle East.
Missing from the picture because on monitoring visits, **Laura**: visiting sites in Spain, France, UK and Ireland, **Caroline**: visiting sites in Germany, Switzerland, Denmark and UK, **Varvara**: visiting sites in France, and **Nada**: visiting sites in France and in the Netherlands.

Why are we proud of our CRAs?

All CERC's CRAs hold an academic degree. At CERC, they benefit from continuous training in interventional cardiology by attending international congress at least once a year, by following internal courses provided by our Medical Directors and by standing in on live interventional procedures at ICPS's cath-lab. With this expertise, CERC's CRAs are 100% involved in our trials, and have a thorough understanding of both background and objectives.

All CERC's CRAs are fluent in at least two languages and most of them are trilingual. Thanks to this, all site management can be centralized in Massy, and we are in a unique position to promote a spirit of collaboration and positive interaction between team members working on different trials. This teamwork enables our CRAs to provide optimal support to all our investigators sites from the first initiation visit to the final trial report. I wouldn't want to work with any other CRAs team.

Laure Morsiani
Clinical Operations Manager

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