The CERC Chronicle

Cardiovascular European Research Center

Issue N°10 May 2015

EDITORIAL

2014 was a very rewarding year for CERC

First of all, we are proud to announce the addition of 2 new prominent members to our founding board: Jens Flensted Lassen from Denmark who replaced Martyn Thomas when he joined the industry and had to leave our group and, more recently, Jean Fajadet from France.

We are confident that their dynamic involvement will further strengthen our company.

As part of our recent achievements, we are presenting many trials in major congresses (Italic at TCT last fall, EBC2, Discovery 1 to 3 and MASTER at Euro-PCR this year) and we have signed several contracts for new very interesting trials.

This has prompted the recruitment of 6 new employees with the subsequent need for larger facilities.

In the wake of last year's success, 2015 has started under favourable auspices with new trials to come.

Marie-Claude Morice

CERC is thrilled to welcome Dr Jean Fajadet and Dr Jens Flensted Lassen

Dr Jens Flensted Lassen
Denmark

Interview with Dr Jean Fajadet

You have just joined CERC's founding members. Do you believe that clinical research will play an increasing part in your practice?

Clinical research should indeed be an essential component of our interventional cardiology practice which is a perpetually evolving field. New generations of stents are constantly being developed, for instance, DES with bioresorbable polymer allowing a reduction in DATP duration or BVS which represent a major advancement.

Such dynamic progress is the result of a fruitful collaboration between manufacturers of new devices and physicians who stimulate research in order to address the unmet needs of their patients. These new technologies must undergo stringent evaluation to ensure that each new device and therapeutic strategy is safe and effective.

Moreover, in the current economic environment of health care cost containment, cost-effectiveness has become an increasingly important parameter. This is in line with CERC's mission and the reason why I am joining their team.

In addition to the field of stents and their associated therapeutic strategies, are there any other domains of clinical research?

Of course! Who could have predicted 10 years ago that 'structural cardiac interventions' would account for 20% of the interventions carried out in the cath-lab.

We are implanting an increasing number of percutaneous valves; the expansion of indications should be conducted with meticulous care in order to ensure that percutaneous treatment is as safe as conventional surgery for our patients.

Even though all patients prefer to be treated with less invasive techniques, thorough assessment via controlled trials is a pre-requisite for further broadening current indications.

Other therapeutic strategies are now being implemented such as transcatheter treatment of mitral valve disease, left atrial appendage and PFO closure, percutaneous management of peripheral arteries and renal denervation, to name but a few.

There are many ongoing studies and many more to come. Our team at the Clinique Pasteur has worked hard to become a reference clinical research investigating center.

By joining CERC, I wish to reinforce my contribution to the shaping of future research endeavors.

Jean Fajadet

CRO Session

Once again this year CERC will be participating in the EUROPCR session dedicated to CRO's. I will have the great pleasure of co-chairing this session with Peter Smits. We will take this opportunity to present some of the most significant studies currently managed by CERC, and especially those likely to bring about changes in medical practice.

We have selected 5 landmark CERC studies.

In the wake of LEADERS FREE, we are now working on the reduction of DAPT duration in patients at high risk of bleeding, with specific focus on a study population of elderly recipients of the Synergy stent : The SENIOR trial (very short DAPT after Synergy stent in elderly patients) will be presented by its PI, O. Varenne.

The ILLUMINA study (Nitides stent, a sirolimus auto-expandable stent in superficial femoral artery and popliteal arteries), whose principal investigator is D Scheinert, is currently assessing the efficacy of a new self-expandable drug-eluting stent manufactured by Alvimedica, in patients with peripheral lesions.

J. Garot will present the BIVAL study designed by the Medicine Company (does Bivalirudine reduce the size of myocardial infarction assessed by magnetic resonance imaging?)

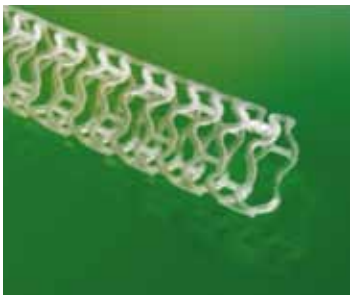
D. Tchétché will talk about the VIVA trial sponsored by Medtronic (CoreValve in valve).

Finally, the Compare Absorb trial (unrestricted grant from Abbott), a large randomized trial comparing the BVS with Xience in the most complex patient and lesion settings, will be delineated by P. Smits.

These studies are currently in the regulatory submission phase or have already entered the enrolment period. The principal investigators will present their protocols and timelines.

Marie-Claude Morice

Trials Focus Compare Absorb



Bioresorbable scaffolds have the potential of becoming the 4th revolution of coronary interventions; however, there is no randomized trial focusing on the treatment of the most complex lesions and patients, and comparing BVS with a metallic gold standard DES.

This is the target of COMPARE ABSORB, an investigator initiated trial conducted by both CERC and Cardialysis under the umbrella of the Foundation for European Research Initiatives in Cardiovascular medicine (FERIC), a nonprofit organization.

The principal investigators are Peter Smits and Robert-Jan Van Geuns with a large steering committee coming from all over Europe.

The main objectives of the trial are to evaluate both non-inferiority for one-year TLF and superiority for one to five years TLF of BVS over Xience in 2,100 patients in European centers.

Secondary analyses include angina evaluation up to one year, cost-effectiveness and patient-related outcome evaluation. Selection of patients is based on the complexity of their profile (diabetes or multivessel disease) or their lesion characteristics (for example, extra-long lesion or total occlusion).

Patients with in-stent restenosis of a drug-eluting stent are admitted to a separate annex study protocol without randomization versus a control group. Another substudy will focus on a new method of following the patients (SMART FU). The trial is now ready to be launched around the time of EUROPCR, and the first patient enrolment is expected for this fall.

Bernard Chevalier

Illumina

Ilumina : Innovative siroLimus seLf expanding drUg-eluting stent for the treatMent of peripheral disease: evaluation of safety aNd efficAcy (Alvimedica and CID sponsors)

Alvimedica
back to life!

CID
Carbostent & Implantable Devices

ILLUMINA is a prospective, multicentre, single-arm and pre-market study. D. Scheinert is the PI.

This study was designed to assess the safety and the efficacy of the NiTiDES stent in terms of vessel patency and composite event-free survival rate up to two years' follow-up in focal/medium length lesions in patients with ischemic obstruction of superficial femoral arteries and proximal popliteal arteries due to de novo lesions .

The primary safety endpoint was defined as the composite event–free survival at 12 months: CEC adjudicated Major Adverse Events (death, target limb amputation, target limb ischemia requiring surgical intervention or surgical repair of target vessel).
The primary efficacy endpoint was defined as primary patency at 12 months: absence of clinically-driven target lesion revascularization or binary restenosis.

The study should enroll 100 patients in 14 European sites.

CERC has been appointed by the Sponsor for the study coordination, the monitoring activities, the SAE reporting, the statistical and data management activities as well as the setting-up of the study.
CERC has been also appointed to manage CEC and DSMB activities

Sabine Monot, Project Leader

Viva

VIVA: Valve In VAlve Trial

This observational, post-market multicenter study was designed to collect real-world data regarding the clinical utility and performance of the Medtronic CoreValve System for TAVI (Transcatheter Aortic Valve implantation) in patients suffering from failing surgical aortic bioprosthesis who are at high risk for redo surgery.

The VIVA study is the first prospective multicenter study dedicated to this specific indication. It is planned to include 200 patients at up to 25 sites (15 French sites, 5 German sites, 3 Italian sites and 2 Israeli sites).

The primary safety endpoint of this study is the occurrence of cardiovascular death at 30 days post-procedure and the primary efficacy endpoint is the absence of significant aortic stenosis or insufficiency at one-year follow-up as assessed by clinical evaluation and echocardiography.

CERC has been appointed as the CRO in charge of the study management and monitoring as well as setting up the CEC and Corelab.

Emilie Chilaud, Project Leader

CERC's Administrative Support Team is in full gear!

As CERC has expanded considerably over the past year, the need has arisen for an Administrative Support Team. In compliance with the recommendations of CERC's management team, seven assistants are now working in close cooperation with the Clinical Project Leaders.

Our main purpose is to work together in order to unify and simplify CERC's administrative tasks and provide our colleagues with robust and reliable support.

The 'assistant' meetings which are held every three weeks have given us the opportunity to share ideas and shape proposals in order to optimize our working time and streamline our administrative workload.

Following our first series of meetings, we listed our respective skills, we set up a post schedule and we created a datasheet for DHL and regular mail. We also identified a major challenge regarding paper waste and launched a subsequent awareness campaign. Our target is to rationalize the use of printed documents in order to reduce paper costs and gain time for other tasks.

In the longer term, so that they can be implemented by all staff members, we have planned to homogenize our filing methods for all trial documentation. The fulfilment of this project should facilitate the work of the whole CERC team.

The objectives of our group are ambitious and require substantial work. However, our high level of motivation, as well as the harmonization of our different personalities into a solid team spirit should strengthen our group and reinforce our creativity and ability to bring our new projects to fruition.

Standing left to right: Gabriela Demeester ; Angele Langlais; Lydie Moutoumalaya. Sitting Left to right: Emilie Cinquegrani; Leslie Fourboul; Stéphanie Taurelle; Isabelle Simoes

We are grateful to our management team for the trust that they have placed in us and for their constant attention to our ideas and proposals.

Stephanie Taurelle and Angele Langlais

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