The CERC Chronicle

Issue No. 21 – May 2022

## CERC at EuroPCR 2022

As a long-standing partner of **EuroPCR**, **CERC** is very pleased that the course has come back to Paris with an exciting educational program.
We are proud to contribute the results of four studies which will be presented during the Late Breaking Clinical Trials sessions:

**ROOM Maillot May 17th 13:30 – 15:00**

**CRUZ-HBR**: all-comer registry on 1203 patients, with 466 at high bleeding risk – **David Leistner**
**MASTER DAPT**: Abbreviated DAPT after complex PCI in high bleeding risk patients – **Marco Valgimigli**

**ROOM Maillot May 18th 8:30 – 10:00**

**REVOLUTION**: Safety and efficacy of robotic-assisted PCI using R-One device – **Eric Durand**
**COMPARE-ABSORB**: BVS vs. metallic DES in diabetic patients: a COMPARE-ABSORB trial substudy – **Giuseppe Tarantini**

## Upcoming Clinical Trials at CERC

B|BRAUN SHARING EXPERTISE

Randomized, controlled trial: DCB vs DES in patients with large CAD in Asia

Medinol Ingenuity for life

### IoNIR

First In Human Study of the IoNIR Ridaforolimus-Eluting Coronary Stent System

Ceric Medtronic

### EVERGREEN

Evaluation of the Valiant Captivia custom made fenestrated stent-graft system for treatment of aortic arch and descending aorta pathologies

ANGIO CARE 安通医疗

### RADIUS-HTN

Renal Artery Denervation Using radial accesS in uncontrolled HyperTensioN Randomizing radial vs. femoral access

ReCor Medical Ultrasound Denervation Therapies

Health technology assessment of RecorMedical renal denervation system in France

## PCR Innovators Day – Competition for the Jon DeHaan Award

Room 251, 10:30 – 12:00
**Electroducer**, the direct wire pacing device. From TAVR to renal denervation – **B. Faurie**

## Meet CERC's CEO and Directors

We would be delighted to meet you to discuss the latest trends in the cardiovascular field, new ideas for clinical research and to share the innovations we are bringing to this area.







COME & MEET US
BOOTH M6
LEVEL 2

2022 euro PCR

## DynamX Bioadaptor

*By Pieter Smits and Candace Elek*

CERC is proud to be involved in two projects with the new DynamX Bioadaptor from Elixir Medical Corporation (USA). The DynamX Sirolimus-Eluting Bioadaptor System (DynamX SECBS), a new class of therapy to treat coronary artery disease, was designed to improve outcomes compared to the current generation DES by restoring normal vessel function .
The DynamX design incorporates novel "uncaging elements" in the implant design (see figure A: DynamX uncaging element). It supports the coronary artery with radial strength and acute performance similar to DES during healing. However, unlike DES, the drug-eluting polymer coating resorbs over 6 months allowing the device to "uncage," restoring normal vessel movement including pulsatility, vasomotion, positive adaptive remodeling as well as vessel rotation and angulation. (see figure B: OCT images demonstrating restoration of pulsatility within the bioadaptor).

The DynamX SECBS is now being evaluated in three clinical studies: a 50 patient European First-In-Men study, the BIOADAPTOR RCT and the INFINITY-SWEDEHEART RCT. The BIOADAPTOR RCT study is a RCT of 445 pts (divided into two cohorts done in Japan and Europe) with the primary endpoint of TLF at 12 months for non-inferiority.

**Figure A**

UNCAGING ELEMENT

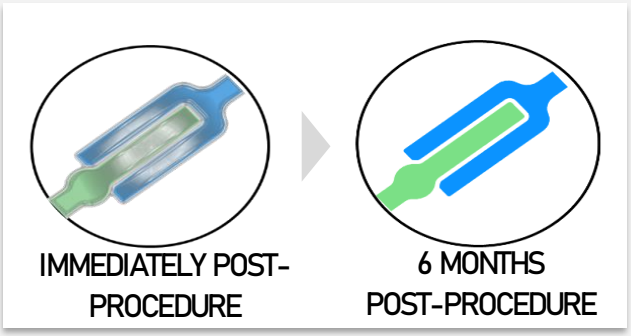
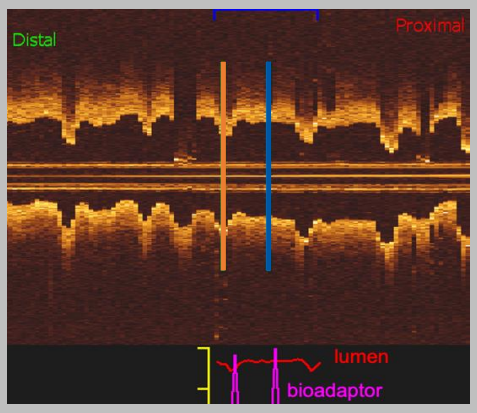
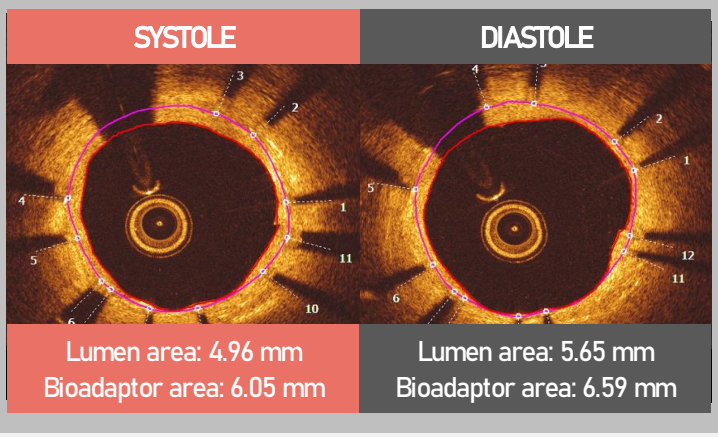



**Figure B**




**14%** increase in lumen area

**9%** increase in bioadaptor area

The INFINITY-SWEDEHEART study is a large scale (2400 pts) registry based randomized trial in a more comer population in Sweden. The INFINITY-SWEDEHEART study has a primary endpoint of TLF at 12 months for non-inferiority and uses an adaptive decision methodology to test for superiority. In both trials the comparator stent is the Resolute Onyx.

Interestingly, the innovation evolves rapidly at Elixir Medical and a triple drug coated stent with Sirolimus and a combination of two anti-coagulation drugs has recently entered clinical testing.

This fascinating concept of potentially limiting systemic drugs around coronary stenting and the fast applicability could have great benefit for high bleeding risk and acute coronary syndrome patients.

'The combination of both new technologies (bioadaptors and anti-coagulation coating) in one therapy opens new avenues for treatment of coronary artery patients in the future' says Mr. **Motasim Sirhan**, CEO of Elixir Medical.

## A Day in the Life of a Clinical Project Leader at CERC

*"Together, we investigate the heart with our heart."*

*By Phani Krishna Kondamudi and Solenne Pavia*

*Solenne:* I am about to start a new position as Clinical Project Leader (CPL) and was looking forward to having a talk about the CPL role. To start with, would you please tell me about the primary responsibilities of a CPL at CERC?

*Phani:* The role of a CPL at CERC is the most exciting and the most comprehensive one. From study design through set-up and execution until the finalization of the clinical trial, the CPL has to strategically navigate all the activities. You can imagine it like the orchestra conductor of a clinical symphony. Our mission is to oversee all the aspects of a clinical trial, from creating the study documents to a final study report, by managing internal and external stakeholders, timelines, budget, the safety of the patients and quality of the data, to name but a few.

*Solenne:* To get more into the heart of the matter, how would you describe a day in the life of CPL at CERC

*Phani:* Every day is different. There is no routine. Diversity of trials: industry or academic partners; diversity of languages and of study

from first in men to sizeable post-market drug and device trials; diversity of personal interactions with research associates, investigators, corelab, data managers, statisticians.... New projects are frequently added. All these multiple tasks require precise planning, identification of priorities and flexibility for the unexpected.

*Solenne:* In addition, what would you say is the most challenging part of a CPL's career?

*Phani:* The exhaustive panel of services provided by CPLs in the entire cycle of clinical trials incorporates strategy, knowledge, and coordination skills. Combining them is already a challenge! But adding care and attention that managing people requires, and close follow-up of the evolution of therapeutic areas doubles the challenges. You cannot overcome all that without passion.

*Solenne:* It seems really exciting! For you, what is the most rewarding aspect

*Phani:* We always keep patients at the HEART of our daily activities, and our ultimate goal is the patient's wellbeing and quality of life and optimal healthcare. It is the right place to be, to have a job that makes a difference in people's lives.

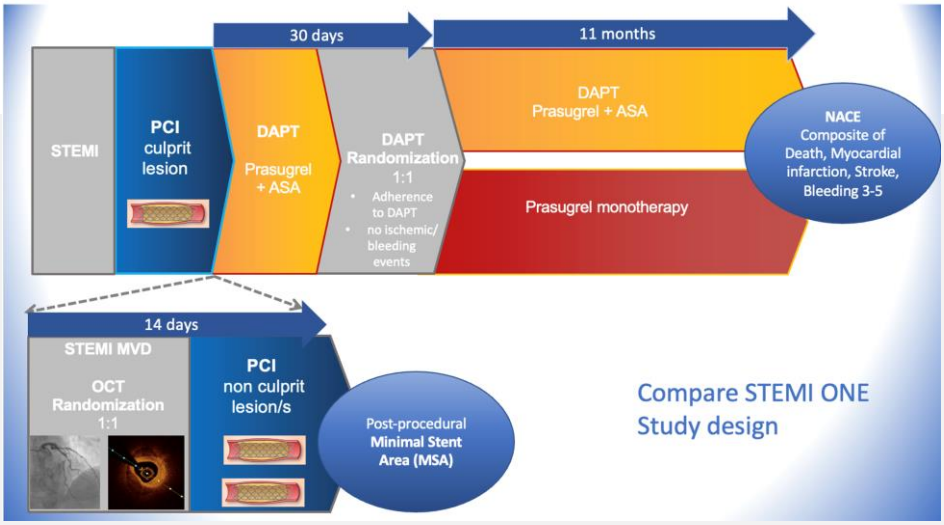
*Solenne:* What makes CERC so distinct from other clinical research organizations?

*Phani:* CERC is a company with a mission, high-quality standards, outstanding care for good clinical research and practice. CERC is unique in providing unparalleled guidance by some of the most renowned experts in the complex cardiovascular field! We benefit from extensive training and education programs allowing growth and career development opportunities. Diversity and inclusion are typical at CERC. Almost one person in three in our organization has a different native language, creating a rich multinational culture that helps our international work and creates a beautiful working environment. CERC is an innovative company, continuously growing and expanding its expertise, making it a most enjoyable place for curious, bright and ambitious people.

*Solenne:* Thank you so much. I am so proud to have joined this exceptional company. I cannot wait to start this journey!

## Compare STEMI One Clinical Trial

*By Valeria Paradies, PI of the study*




COMPARE STEMI ONE (Comparison Of reduced DAPT followed by P2Y12 inhibitor Monotherapy with Prasugrel vs stAndard Regimen in STEMI patients treated with OCT-guided vs aNgio-guided completE revascularization) is a randomized multicenter trial comparing an abbreviated dual antiplatelet therapy (DAPT) regimen (1 month) followed by Prasugrel monotherapy to standard DAPT in STEMI patients. In multivessel disease (MVD) patients, non culprit lesions will be allocated to either angio- or Optical Coherence Tomography (OCT)-guided PCI.

The main hypotheses of the study are:

1. noninferiority of Prasugrel-based short DAPT (30-45 days) followed by Prasugrel monotherapy versus Prasugrel-based standard DAPT therapy concerning the pre-specified primary endpoint of NACE defined as death, MI, stroke, or bleeding BARC 3-5 at 11 months (randomization of patients who remain stable on DAPT and without ischemic or bleeding events at 30-45 days after index procedure)
2. the superiority of OCT-guided versus angiography-guided complete revascularization in terms of post-PCI minimal stent area (MSA).

Advances in stent technologies, with thinner struts drug-eluting stents (DES), bioresorbable polymer promoting vascular healing and endothelial repair, have significantly reduced the rate of thrombotic complications and may justify a shorter DAPT duration. Whereas in stable patients a progressive shortening of the antiplatelet treatment has been extensively investigated in RCTs, a similar approach could not be directly translated to patients admitted with ACS.

In high bleeding risk patients of the MASTER DAPT trial, one month of DAPT was non-inferior to standard DAPT regimen in terms of NACE and MACE and was associated with a lower incidence of

major or clinically relevant non-major bleeding[1]. More recently, the hypothesis that acetylsalicylic acid-sparing regimens based on the availability of newer antithrombotic agents may increase net benefit for individual patients owing to the reduction in bleeding risk, without a trade-off in efficacy, is investigated. Two meta-analyses confirmed this trend[2,3]. However, limited data are currently available on ACS patients.

The use of intravascular imaging in the context of complete revascularization and short DAPT regimen has received limited attention. OCT may be a useful tool for providing information on pre-intervention lesion characteristics; on postintervention optimal stent implantation for stent expansion and apposition; and on possible complications after stent implantation. The interactions between short DAPT regimens and potential underlying stent abnormalities for ST remain largely unknown; even though different mechanical substrates such as uncovered/poorly healed struts could favor a rheological environment that might enhance thrombogenicity.

The current study design of Compare STEMI One will delineate the interaction between a reduced DAPT strategy and an optimal stent implantation strategy OCT-guided in STEMI patients with MVD.

MAASSTAD ZIEKENHUIS een santeon ziekenhuis **Sponsor**

Abbott **Grant Giver**

We at CERC are very proud to conduct this interesting study. Our high expertise in DAPT trials will help accelerate all study phases to ensure timely results which might change clinical practice.

**Dr Valeria Paradies** is an interventional cardiologist working at Maasstad Hospital, Rotterdam; currently enrolled in a PhD program at Erasmus Medical Centre University in Rotterdam. Author of 57 papers published in peer-reviewed journals, three book chapters and 70 abstracts presented at international conferences, she is currently local PI of 15 RCTs.


1. Valgimigli M. et al. MASTER DAPT Investigators. Dual Antiplatelet Therapy after PCI in Patients at High Bleeding Risk. N Engl J Med. 2021 Oct 28;385(18):1643-1655
2. Giacoppo D. et al. Short dual antiplatelet therapy followed by P2Y12 inhibitor monotherapy vs. prolonged dual antiplatelet therapy after percutaneous coronary intervention with second-generation drug-eluting stents: a systematic review and meta-analysis of randomized clinical trials. Eur Heart J. 2021 Jan 21;42(4):308-319
3. Valgimigli M. et al. P2Y12 inhibitor monotherapy or dual antiplatelet therapy after coronary revascularisation: individual patient level meta-analysis of randomised controlled trials. BMJ. 2021 Jun 16;373:n1332.


## Late-Breaking News

### The first patient enrolled in PiCSO-AMI-V Clinical trial

**PICSO-AMI-V** is a prospective, randomized, multicenter feasibility study in patients with inferior STEMI presenting with TIMI 0 & 1 flow. The patients will be randomized 2:1 to a group receiving PiCSO (Pressure-controlled intermittent Coronary Sinus Occlusion, Miracor) as an adjunct to their primary PCI procedure versus a conventional strategy of primary PCI alone.

## CERC's family is growing

*By Marie Claude Morice, CEO*

With a growing number of clinical trials at CERC we are thrilled to welcome new, young and brilliant members who will take up various positions in our team. They will be collaborating with you from now on. We wish success and above all, great satisfaction to our new members, and our precious partners.


Tom


Chloé


Eleftheria


Wesley


Léa


Maëlys

Esther, Sophie, Khady, Mathis & Mathias


Solenne


Ermela


Alex


Marianne


Julie


Linh


CERC
7, rue du Théâtre
91300 Massy - France
Tél : +33 (0)1 76 73 92 10
Fax : +33 (0)1 60 11 17 91
www.cerc-europe.org
CERC
CERC_CRO