EMBARGOED UNTIL 23 May, 09:40 CEST

PCR statement on device-based therapies for hypertension

Meeting current challenges in managing hypertension today

EuroPCR 2018, the annual Course of the European Association of Percutaneous Cardiovascular Interventions (EAPCI), a branch of the European Society of Cardiology (ESC), will take place in the Palais des Congrès in Paris, France, from 22 to 25 May.

"I don’t think the medical community fully appreciated the seriousness of the adherence problem in hypertension before the device-based clinical trials, which only reinforced the previous findings that adherence gets worse with the increasing number of antihypertensive medications a patient is taking."

- Prof. Felix Mahfoud, MD, FESC

Paris, France, 23 May 2018. Despite the best efforts of clinicians to manage hypertension, it continues to increase and is now reaching epidemic levels worldwide with >1 billion patients considered to be suffering from hypertension today. Despite the availability of many safe and effective drugs, the control rates remain unacceptably low.

We know that half of the hypertensive patients become non-adherent in the first year after initiation of drug treatment and about 20% are completely non-adherent. In recent years, clinical trials for device-based treatment of hypertension have further underlined the seriousness of this adherence problem for the medical community as a whole, especially “reinforcing earlier findings that adherence gets worse with the increasing number of anti-hypertension medications a patient is taking.”
Today, faced with the challenge of finding viable solutions to this public health issue, the concept of device-based treatments remains promising and is under careful investigation. The continued evolution in the devices and techniques themselves, along with a deepening understanding of patient selection have the potential to lead us to new insights into possible treatment options for this disease.

There is renewed interest in renal denervation therapies, as emerging data further illuminate the different mechanisms at work in these treatments and demonstrate their therapeutic value.

During the ESC annual meeting last year, important data were presented which demonstrated statistically significant and clinically meaningful reductions in blood pressure following renal denervation (RDN) in patients not taking anti-hypertension medications, either throughout medication washout or in the treatment of newly diagnosed hypertensives. Also, an ambulatory blood pressure monitoring (ABPM) analysis, presented at the 2017 ACC Scientific Sessions, showed that renal denervation is “always on”, even during high-risk periods such as in the early morning hours, when a drug’s effect may be subsiding or absent.

This year, at EuroPCR 2018, two important studies will be presented on renal denervation for hypertension treatment which will be simultaneously published in The Lancet. We feel that these two studies finally provide biological proof of principle of a device-oriented approach to modulate renal nerve activity and thereby lower blood pressure:

- The prospective, randomised, sham-controlled **SPYRAL HTN-ON MED study** investigated renal denervation using a radiofrequency device in the presence of antihypertensive drugs, confirming the effectiveness of blood pressure lowering in combination with pharmacotherapy (1-3 drugs). Eighty patients were
randomised and followed through six months. Office and 24-hour ambulatory BP decreased significantly from baseline to six months in the renal denervation group (24-hour SBP -9.0 mmHg, 24-hour DBP -6.0 mmHg, office SBP -9.4 mmHg and office DBP -5.2 mmHg).

- The prospective, randomised, sham-controlled RADIANCE-HTN SOLO study used an ultrasound catheter to achieve renal denervation. A total of 146 were randomised to renal denervation (n=74) or sham procedure (n=72). Using this device, the investigators have now documented significant changes in office and ambulatory blood pressure following renal denervation, but not in the sham treated patients (baseline-adjusted difference between groups: -6.3 mmHg). The primary efficacy and safety endpoints of this trial were met.

What do we see for the future?
For any therapy to be effective it is critical to understand which patient will – or will not – respond favourably to the technique. The data being presented during EuroPCR 2018 should inspire new approaches to answering these questions. While there are some interesting hypotheses and views in the community, for the moment we look forward to continued preclinical and clinical investigations and research which will hopefully allow us to further define patient selection for RDN. Other unanswered questions concern procedural parameters for successful renal denervation or whether the proven blood pressure-lowering effects are sustainable at long-term follow-up.

In conclusion, despite decades of effort to control hypertension through lifestyle adjustment and medication, the challenge remains. There is a huge unmet need. New approaches are critical and needed in order to increase control rates and reduce patient risk. Progress exists, the work continues.
CONTACT

Prof. Dr Felix Mahfoud, MD, FESC
Department of Internal Medicine III
Cardiology, Angiology, Intensive Care Medicine
Saarland University Hospital
Kirrberger Str. 1, IMED, Geb. 41
66421 Homburg/Saar
Germany
Tel: +49 6841 16 15350
Fax: +49 6841 16 15910
Email: Felix.Mahfoud@uks.eu
www.uks.eu/kardiologie

EuroPCR 2018 Session

Wednesday 23 May - Main Arena

9:40   SPYRAL HTN-ON MED: six-month results from the randomised, blinded, sham-controlled trial on renal denervation in the presence of antihypertensive medications - David Kandzari

9:55   RADIANCE-HTN SOLO: primary outcomes of renal denervation - Laura Mauri
HELP FOR JOURNALISTS TO COVER EUROPCR 2018

For any press-related inquiries, please contact
EuroPCR Press Coordinator, Isabelle Uzielli: iuzielli@europcr.com

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NOTES TO EDITORS

What is EuroPCR?
EuroPCR is the world-leading Course in interventional cardiovascular medicine, and the official annual meeting of the European Association for Percutaneous Cardiovascular Interventions (EAPCI), a branch of the European Society of Cardiology (ESC).

In addition to this flagship course in Paris, PCR offers a large range of many other educational meetings and resources for the continuing education of the interventional cardiovascular community. These include major annual Courses across the globe, E-Learning with high-profile PCR Webinars, Courses specifically dedicated to valvular heart disease, tailor-made PCR Seminars on specific topics, online resources and medical publications such as EuroIntervention, the official journal of the EAPCI.

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For further information, please contact Célia Vilà: cvila@europa-group.com