# European consensus group calls for standards to move renal denervation field forward

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Experts participating in a European Clinical Consensus Conference (CCC) have concluded that research into the use of renal denervation for high blood pressure in patients unable to control the disease using a multi-drug regimen should not be abandoned until high-quality research is completed according to agreed-upon standards.

"Focused, collaborative high-quality research will be necessary to ensure that future patients are neither denied an effective therapy, nor needlessly put at risk from procedures that bring no benefits," the authors, led by Dr. Felix Mahfoud of Saarland University Hospital, Homburg/Saar, Germany, write.

The group's conclusions, including a roadmap for future research into non-drug treatment for resistant hypertension, is published today in the *European Heart Journal* and are the focus of a special session Wednesday at EuroPCR 2015.

Observational studies as well as three randomised, controlled trials support the safety and efficacy of the therapy, but smaller studies as well as the large, single-blind, randomised, sham-controlled Symplicity HTN-3 trial failed to show any benefit to renal denervation. The therapy uses radiofrequency energy or other ablation methods, delivered by a catheter, to disrupt the nerve signals travelling to and from the kidney, with the aim of lowering systolic blood pressure. In the wake of the

Symplicity HTN-3, some clinicians have refused to endorse the procedure. Others, pointing to a significant unmet need, have argued it's too soon to abandon the investigative procedure, the CCC paper notes.

In their consensus document, Mahfoud and colleagues examine procedural aspects, patient selection, and clinical trials, reaching a number of important conclusions.

- At the procedural level, practitioners have learned that getting effective results with renal denervation is not as simple as it first seemed, particularly as it applies to achieving "complete" ablation. Better preclinical studies are needed, as are reliable markers to determine whether or not nerve ablation has been successful.
- In terms of the appropriate patient group, the CCC concluded that selecting "last resort" patients with high systolic blood pressure taking three or more drugs may not necessarily be the best patients in whom to use or indeed study the emerging therapy. Younger patients with moderate hypertension might actually have anatomy more suited to lasting results.
- With regards to appropriate clinical trials, the CCC strongly supports the use of ambulatory blood pressure monitoring, both to determine the response to renal denervation, but also as a prerequisite for enrolling a patient in a RDN study. Other key factors for future research include how to measure adherence to blood pressure drugs, and how to standardize treatment during the study "run-in period." Finally, the requirement of using a sham-control procedure—and its inherent risks—may need to be dispensed with if lower-risk hypertension patients are studied, they propose.

Most of all, renal denervation research is in desperate need of standardization, the authors write. "Treatments, populations, methods,

and adherence measures need to be highly consistent to avoid inconclusive or biased results."

"The open questions around renal denervation touch upon a large number of specialties from interventional cardiologists to hypertension experts and molecular biologists," Dr. Mahfoud commented. "The future of the therapy will depend on closer interactions at all levels, necessitating focused collaborative high-quality research, smaller projects targeting specific questions as well as large-scale multidisciplinary research programmes."

**More information:** Mahfoud F, Bohm M, Azizi M, et al. Proceedings from the European clinical consensus conference for renal denervation: considerations on future clinical trial design. Eur Heart J 2015; DOI: DOI: 10.1093/eurheartj/ehv192

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