- My name is Felix Mahfoud, I'm professor of medicine and a cardiologist working at Hamburg/Saar, Germany.

Importance of the SPYRAL HTN-ON MED Pilot Study

Well, we all know that high blood pressure is worldwide risk factor number one, thus, by the availability of safe and effective antihypertensive drugs and lifestyle modification, many patients remain uncontrolled. So there is an unmet need for additional treatment approaches to lower blood pressure in hypertensive patients, and the SPYRAL ON-MED study investigated catheter-based renal denervation in uncontrolled hypertensive individuals treated with one, two, or three antihypertensive drugs.

Design, Patient Cohort and Endpoints

This study included patients with uncontrolled hypertension. Office blood pressure was in between 150 to 180, ambulatory blood pressure was in between 140 to 170, and patients were treated with guideline recommended drug therapy. Indeed, they received one, two, or three antihypertensive drugs, and despite the intake of these drugs, they were uncontrolled. We randomised these patients to an invasive placebo, a sham, and renal denervation using a radio frequency catheter and we followed these patients out to three years.

Key Findings

So first we showed a continued and progressive decline in blood pressure over time. Ambulatory blood pressure was reduced up to 19 millimetres of mercury at 36 month of follow up, and that was significantly larger as compared to the sham group. Although medication was no different between the two groups, when you carefully look into it, detailed look into it, you'll appreciate that the sham group numerically received more drugs although their blood pressure lowering was less pronounced than in the denervation group. And that adds to the knowledge of renal denervation, that indeed, in combination with antihypertensive agents, you can appreciate a significant reduction in blood pressure.

Influence on Guideline Recommendations

This is another piece of the puzzle, adding to the evidence that renal denervation effectively and safely lowers blood pressure in hypertensive patients. We have to documented this in patients without concomitant antihypertensive drugs, we have seen it in patients with antihypertensive agents, one, two, or three, and even on a triple fixed combination. And we have a large cohort of patients being treated in a registry, so 3000 patients. And again, this is a piece of the puzzle showing that in a sham-controlled fashion, you appreciate a sustained reduction in blood pressure, even a progressive reduction in blood pressure out to three years, and that speaks to the relevance of the sympathetic nerves and the capability of renal denervation to lower blood pressure, even over time.

Remaining Questions and What is Left for Renal Denervation

There is an extension to that SPYRAL ON-MED study ongoing with another 260 patients being randomised. And other continued access programme trials are ongoing, registries are ongoing, and these will complement the evidence. I think we have achieved a significant and we have acquired a significant body of evidence indicating that it is efficacious and safe in lowering blood pressure, and that this is an attractive and alternative treatment option in patients with hypertension.

Take-home Messages

So this is an important piece of evidence, because it shows in a sham-controlled fashion that denervation can lower blood pressure out to three years, so there is no indication of reinnervation of sympathetic nerves, functional reinnervation of sympathetic nerves. And it also shows that when you add denervation to medication you can appreciate really significant and clinical meaningful reductions in blood pressure, as said, 20 millimetre of mercury reduction. That's a really important number, that is relevant for patient care.