My name is Felix Mahfoud, I'm a cardiologist working here at the Saarland University Hospital in Hamburg Saar, Germany.

What is the rationale behind this study?

Well, the Global Symplicity registry is the largest and longest follow-up population of real world patients with uncontrolled hypertension treated with radiofrequency renal denervation. And the objectives of the registry are to assess the long-term safety and effectiveness of the Symplicity renal denervation system. With renal denervation, we very often see different clinical benefits that may be measured by multiple variables such as office and/or ambulatory blood pressure reductions. But often, also, we document a change in antihypertensive medication burden. The win ratio analysis enables evaluation of clinical benefits based on multiple variables and a hierarchical composite endpoint. And that was the purpose of the study.

What is the design, patient cohort and endpoints?

We use the Global Symplicity registry, which is the largest and longest follow-up population of real-world patients with uncontrolled hypertension. And in this cohort, we assessed using a win ratio methodology the impact of renal denervation on various endpoints in patients who are elderly, in patients with diabetes, and in patients with chronic kidney disease.

What is the win ratio methodology?

Because very often after renal denervation, the outcomes, the changes, are quite variable. One patient may show a reduction in office blood pressure, another patient may show no change in blood pressure but a decrease in ambulatory blood pressure. And another, a third patient, may show no change in blood pressure, no reduction in ambulatory blood pressure, but decreases antihypertensive medication burden throughout follow-up. All of these are important endpoints, and the win ratio analysis enables to assess these outcomes using a hierarchical analysis.

What are your key findings to date?

First, we documented significant office and 24 hour ambulatory blood pressure reductions that sustained throughout three years in the Global Symplicity registry in more than 2,800 patients. We also documented, using the win ratio analysis, ranking office 24 hour blood pressure reductions and medication changes. Additional insights into the benefits of renal denervation in high-risk cohorts. And these cohorts suffered from diabetes or chronic kidney disease, or were elderly individuals indeed above 65 years of age. And what we found were, that patients were equally likely to experience a reduction in office, ambulatory, and/or medication burden between these high risk subgroups. And importantly, a new study, the GSR-DEFINE, will include patients very shortly and will extend our knowledge about renal denervation when used in real world experience.

What conclusions can be made, and what should be the impact on practice?

The results from the win ratio analysis demonstrate comparable probability of responding to renal denervation therapy regardless of age, chronic kidney disease, or diabetes status. Indicating similar efficacy based on ambulatory, office blood pressure and/or medication burden between these high risk patient cohorts.

What are the next steps?

The Global Symplicity registry will now be followed and extended by the new GSR-DEFINE study that will expand our knowledge on renal denervation when used in clinical practise in over 5,000 real world patients treated with radiofrequency catheter-based renal denervation.