- Hi, I'm Ajay Kirtane. I'm an interventional cardiologist at Columbia University Medical Centre, New York Presbyterian hospital in New York. And I'll be talking today about a pooled analysis that we presented as a late breaking trial for EuroPCR on the radiance-HTN programme.

Study Background

I think there's been a lot of excitement about renal denervation and the idea that renal denervation could potentially reduce blood pressure. We conducted two independent randomised controlled trials of renal denervation versus a sham control. And we sought to pool the results together today to be able to determine if we could make any general messages across both trials.

Study Design & Patient Selection Criteria

Patients for radiance-HTN solo and trio consisted of two separate cohorts of patients. All patients did have to have elevated blood pressure but at least in the solo cohort, these were patients who could be safely taken off their medications for a short time to determine the effect of denervation versus sham on a background of no medications. Radiance-HTN trio on the other hand, took patients that were hypertensive despite being on three or more medications. And so they were actually transitioned to a single combination therapy pill of a thiazide diuretic calcium channel blocker and an angiotensin receptor blocker. Once they were stabilised and still found to be hypertensive they could then be randomised to denervation versus sham. So what we basically sought to do is to determine if the effect of denervation versus sham was consistent without heterogeneity across those two independently derived patient populations.

Key Results

The key results of this analysis, and remember these were patients who were kept on fixed medical regimens or no medicines for the solo cohort for one month and then randomly assigned to denervation versus sham followed for an additional two months to determine the true treatment effect of the therapy. Between two and six months, medications were added back to their regimens in order to achieve better levels of blood pressure control. What we showed is that at two months, there was a clear drop in blood pressure in both study groups, denervation arm relative to sham, and at six months less medications needed to be added back to those patients who were randomly assigned to the denervation group. Notably though, despite less medicines being added back, blood pressures were lower at six months across the entire study period in the denervation group compared to the sham group. In fact, from baseline to six months in the denervation group, blood pressure dropped by 13 millimetres of mercury. For these patients that had started off at blood pressures of 150 and above, that's a meaningful difference. But that's really a combined effect of denervation plus medications. When you compare it to sham plus medications, the difference in daytime ambulatory systolic blood pressure and home systolic blood pressure was approximately five millimetres of mercury but yet this was highly significant when pooled across both populations. So in summary, what we showed is that the treatment effect was very similar in both studies, despite differing levels of hypertension. And despite the fact that this was on meds and off meds. And so in a sense, renal denervation would work similarly independent of the severity of hypertension and independently of medicines being added or not.

Which Patients Would Benefit from RDN and Considerations

Well, because it's an invasive procedure, you have to be cautious about whom you offer renal denervation to. And so in general, we know medicines and lifestyle modification work very well. And so these were really going to be patients who despite medicines and lifestyle can't tolerate further additions and still remain uncontrolled. For those patients, renal denervation seems to be a quite an attractive alternative. We do have to make sure that long term safety data is holding up and showing there are no deleterious effects of the procedure, but to date that doesn't seem to be an issue. And so my sense is that for patients that have difficult to control blood pressure or those who are unable to tolerate medications, this might offer a good alternative.

Take-Home Messages

To me, the take home messages are really important, especially because today is World Hypertension Day. We know that blood pressure is difficult to control and there are many patients that have poorly controlled blood pressure. Renal denervation through several sham controlled studies has been shown to effectively lower blood pressure. And therefore that offers a complimentary addition to what we already have today to treat our patients. So for patients whose blood pressure is difficult to control or have challenges taking medicines, this is an important adjunct that will likely be approved in the next few years and giving our physicians an additional option to treat blood pressure.

Next Steps

The key next steps for these devices are several. I think first, we need longer term safety data from all programmes and that's ongoing. Second, we need the pivotal approval trials to be completed and we hope that will happen in the next year. And then ultimately these devices will then be approved certainly in the United States and then perhaps abroad. Finally, we'll need better treatment pathways to determine exactly where in the pathway or the patient journey renal denervation can be offered. Because again, just because you have something that potentially works, doesn't mean it should be first line. I still personally think that lifestyle modification and medications might be first line for these patients. But yet, at some point renal denervation should be considered and potentially offered to help control blood pressure better.