

interventional therapies for hypertension: current status

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### **Abstract**

Comprehensive subanalyses of the results of Symplicity HTN-3 in combination with novel preclinical data regarding the location and distribution of renal fibres improved the insight on the confounding factors of renal denervation (RDN) therapy. The recently published results of the “second generation” sham-controlled randomized RDN trials address successfully the above.

In the Spyral HTN-OFF MED trial patients were off any antihypertensive medication with office BP > 150/90 mmHg, and 24-hour ambulatory systolic BP > 140 mmHg. Spyral-HTN ON Med included patients with the same BP criteria but 1-3 antihypertensive medications were allowed. In both studies more than 45 ablations were performed per patient with the Spyral multielectrode over-the-wire radiofrequency system. In the Spyral HTN-OFF Med trial, 24-hour ambulatory BP was reduced by -5.5/-4.8 mmHg in the RDN group and -0.5/-0.4 mmHg in the sham group after 3-months. The mean baseline-adjusted difference in ambulatory BP between the RDN and the sham groups was -4.6/-4.3 mmHg for 24-ambulatory BP. In the Spyral HTN-ON Med, 24-h ambulatory BP was reduced in the RDN group by -9.0/-6.0 mmHg after 6 months, compared to changes of -1.6/-1.9 mmHg in the sham group. The mean difference in 24-h ambulatory BP was -7.0/-4.3 mmHg. The mean baseline-adjusted differences in office BP between the RDN and the sham group were -7.1/-5.0 mmHg in Spyral HTN-OFF Med and -6.6/-4.2 mmHg in the Spyral HTN-ON MED. There was a stable reduction of 24-h BP in the RDN group whereas this was not present in the drug intervention arm, suggesting an “always-on” effect of RDN on BP levels. Regarding safety there were no adverse events throughout the reported follow-up. These proof-of-concept Spyral studies provided the evidence for larger pivotal studies.

In the Radiance HTN-SOLO all patients were off antihypertensive medication and inclusion criteria were office BP  $\geq$  140/90 mmHg and daytime ambulatory BP  $\geq$  135/85 mmHg. The

Radiance-HTN trial used a low-pressure water-filled cooling balloon catheter that delivers ultrasound energy for thermal ablation. In the Radiance SOLO trial daytime ambulatory BP was reduced by -8.5/-5.1 mmHg in the RDN and -2.2/-2.6 mmHg in the sham group. The mean baseline-adjusted difference in ambulatory BP between the RDN and the sham groups was -6.3/-2.6 mmHg for daytime ambulatory BP. The mean baseline-adjusted differences in office BP between the RDN and the sham group were -6.5/-4.1 mmHg. There were no major adverse events in the Radiance HTN-SOLO trial.

The results of these “second generation” sham-controlled studies provide evidence for effectiveness and safety of RDN therapy in the presence or absence of antihypertensive drugs. The reported reduction of both office and ambulatory BP is consistent throughout these trials and is clinically meaningful in terms of cardiovascular risk reduction. Further larger scale studies are needed to guide future recommendations for RDN in essential hypertension.