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Proposal for a novel definition of "Ideal Response" to renal denervation and analysis of the optimal length of follow-up

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Introduction: Renal Denervation (RDN) has been shown to be an effective treatment option for patients suffering from resistant arterial hypertension in numerous unblinded clinical trials. However, as the randomized sham-controlled Symplicity HTN-3 trial had failed to achieve its primary efficacy endpoint, new studies like the Spyral HTN Global Clinical Trial were designed to address possible confounding factors like drug changes and adherence, as well as patient population and procedural variability. In this regard, the definition of response to treatment is crucial for the evaluation of the effect of RDN. In previous clinical trials, adequate response was defined as a reduction of the mean systolic ambulatory blood pressure of more than 5 mmHg at merely a single follow-up point after six months. As it was observed, that patients fulfilling this criterion showed increased blood pressure levels at other time points of follow-up, this approach may not reflect a sustained blood pressure reduction. Therefore, we redefined the criteria for ideal respondership and tried to evaluate the optimal duration of follow-up after renal denervation.

Materials and Methods: Patients with resistant hypertension were treated with RDN. Resistant hypertension was defined as a mean systolic office BP > 160 mmHg after three measurements. All patients had to be on at least three antihypertensive drugs including one diuretic and secondary causes of hypertension were ruled out prior to the procedure. For RDN, the Symplicity[™] RDN Catheter System (Medtronic Inc., Minneapolis, MN, USA) was used. Depending on renal artery anatomy, a maximum of 10 ablations were performed in each renal artery, respectively. The individual patient blood pressure course after RDN was monitored by scheduled follow-up visits after 3, 6, 12 and 24 months. At all visits, including baseline, ambulatory blood pressure measurement (ABPM) was performed using the "Del Mar Reynolds Medical ABPM System" (Version 2.08.005). According to the assumption that an ideal responder should have lowered BP levels at every visit after RDN, response to RDN was defined as a sustained reduction of the mean systolic blood pressure of at least 1 mmHg at each follow-up-visit compared to baseline levels. The number of patients fulfilling this definition was obtained by analyzation of their individual blood pressure course in order to evaluate the rate of sustained blood pressure reduction as well as to assess the optimal duration of follow-up necessary for the proposed novel definition of ideal respondership.

Results: We investigated the effects of RDN on blood pressure levels in 42 patients suffering from resistant hypertension. 11 of these patients were excluded after baseline ABPM had revealed pseudo-resistance with a mean systolic blood pressure <130 mmHg. By consideration of the proposed novel definition of "ideal response", 12 of 31 patients (38,7%) could be classified as ideal responders after 24 months. In this collective, there was a significant mean systolic blood pressure reduction at all follow-up points (3M: -21,4 mmHg, p<0,01; 6M: -15,8 mmHg, p<0,01; 12M: -19,9 mmHg, p<0,01; 24M: -22,8 mmHg, p<0,01). Of the 13 patients that could be classified as ideal responders after 12 months, 12 patients (92,3%) fulfilled the criteria with a sustained blood pressure reduction after 24 months.

Discussion: As more than 90% of all patients undergoing RDN that met the definition of "ideal response" after 12 months were also ideal responders after 24 months, a follow-up period of 12 months seems to be adequate to confirm sustained blood pressure reduction in patients undergoing RDN.

Biography

Christian Reiter has completed his MD at the age of 25 years graduating from Medical University of Vienna (Austria) in 2012. Subsequently, he undertook his internship in general medicine at the General Hospital in Linz (Austria) until the start of his residency at the Department of Cardiology and Medical Intensive Care Medicine of the Kepler University Hospital Linz (Austria) in September 2015. He has collaborated in several studies published in reputed journals, especially in the field of resistant hypertension.

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