Endovascular ultrasound renal denervation to treat hypertension (RADIANCE-HTN SOLO): a multicentre, international, single-blind, randomised, sham-controlled trial

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RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Azizi M, 2018	RCT	?? ?	+	+	+	?

Characteristics of studies

Azizi M, 2018

Population	1. Added value of this study The RADIANCE-HTN SOLO trial was designed to show the effect of endovascular ultrasound renal denervation on ambulatory blood pressure compared with a sham procedure in patients with combined systolic‚Äìdiastolic hypertension who were off antihypertensive medications. 2. Patients also needed to have an estimated glomerular filtration rate (eGFR) of greater than or equal to 40 mL/ min per 1¬∑73 m¬≤ (based on the Modification of Diet in Renal Disease formula) and no history of cardio vascular or cerebrovascular events. 3. This study was powered for efficacy and our results showed a greater reduction in daytime and 24-h systolic ambulatory blood pressure at 2 months in patients who underwent renal denervation than in patients who underwent a sham procedure.
Intervention	1. Added value of this study The RADIANCE-HTN SOLO trial was designed to show the effect of endovascular ultrasound renal denervation on ambulatory blood pressure compared with a sham procedure in patients with combined systolic‚Äìdiastolic hypertension who were off antihypertensive medications.
Outcomes	1. Each cohort was independently powered to detect a difference between renal denervation and the sham procedure in terms of the primary endpoint, of change in daytime ambulatory systolic blood pressure at 2 months. 2. This study was powered for efficacy and our results showed a greater reduction in daytime and 24-h systolic ambulatory blood pressure at 2 months in patients who

underwent renal denervation than in patients who underwent a sham procedure.
3. Additional prespecified safety endpoints included hypotensive emergency; hospital admission for heart failure; stroke, transient ischaemic attack, or cerebro vascular accident; acute myocardial infarction (ST-elevation myocardial infarction or non-ST elevation myocardial infarction); any coronary revascularisation; procedure-related pain lasting longer than 2 days; new renal artery stenosis greater than 50% by duplex ultrasound and confirmed by renal CT or MR angiography; and need for renal artery angioplasty and, stenting, or both.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. The randomisation sequence was computer generated and stratified by centres with randomised blocks of four or six and permutation of treatments within each block. 2. The randomised treatment assignment was accessible only to the staff responsible for performing the procedures through dedicated web-based software. 3. Five patients in the renal denervation group and 13 in the sham group were treated with antihypertensive medications before the 2-month ambulatory blood pressure measurement by physicians masked to treatment assignment: one patient in the renal denervation group and three patients in the sham group were treated after meeting protocol-defined escape criteria, whereas four and ten patients, respectively, were treated on the basis of the physician's decision or patient preference, despite not meeting protocol-defined criteria).
Allocation concealment	low	1. The randomisation sequence was computer generated and stratified by centres with randomised blocks of four or six and permutation of treatments within each block. 2. The randomisation assignment was masked for 6 months after randomisation for patients, outcome assessors, and clinicians involved in follow-up care. 3. The randomised treatment assignment was accessible only to the staff responsible for performing the procedures through dedicated web-based software.
Blinding of participants and personnel	low	1. The randomisation assignment was masked for 6 months after randomisation for patients, outcome assessors, and clinicians involved in follow-up care. 2. *Abdominal obesity status not available in one patient in renal denervation group, eGFR data were unavailable in one patient in the renal denervation group and three patients in the sham group, and sleep apnoea status was unavailable in one patient in the sham group. 3. Patients completed a questionnaire to assess the effectiveness of masking at discharge and 2-month follow-up.
Blinding of outcome assessment	high/unclear	1. For the analysis of the primary endpoint in the ITT population, patients who met the protocol criteria for antihypertensive drug treatment before 2 months and patients with missing 2-month ambulatory blood pressure data were assigned their baseline value of daytime ambulatory systolic blood pressure at 2 months. 2. For this patient, independent review of their preprocedural and 6-month postprocedure renal artery imaging showed that there was a pre-existing ostial renal artery stenosis (40,Äì50% on MR angiography, 44% on renal angiography), which would have met the criteria for exclusion but was not recognised at the time of randomisation, and a 57% ostial renal artery stenosis on renal angiography before renal artery stenting at 6 months.

3. All antihypertensive medications were discontinued for 4 weeks before the Research in context Evidence before this study We searched PubMed up to April 15, 2018, without time or language restriction with the terms " renal denervation " , " hypertension " , " randomised " , " hypertension " , and various combinations of those words to identify systematic reviews, meta-analyses, and randomised controlled trials of blood pressure lowering efficacy of renal denervation.

References

1. Azizi M et al. Articles Endovascular ultrasound renal denervation to treat hypertension (RADIANCE-HTN SOLO): a multicentre, international, single-blind, randomised, sham-controlled trial N. Engl. J. Med. 2018. 370(15); 1393-401 PMID: 24678939