

Documents

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Abstract

Background: Endovascular renal denervation reduces blood pressure in patients with mild-to-moderate hypertension, but its efficacy in patients with true resistant hypertension has not been shown. We aimed to assess the efficacy and safety of endovascular ultrasound renal denervation in patients with hypertension resistant to three or more antihypertensive medications. **Methods:** In a randomised, international, multicentre, single-blind, sham-controlled trial done at 28 tertiary centres in the USA and 25 in Europe, we included patients aged 18–75 years with office blood pressure of at least 140/90 mm Hg despite three or more antihypertensive medications including a diuretic. Eligible patients were switched to a once daily, fixed-dose, single-pill combination of a calcium channel blocker, an angiotensin receptor blocker, and a thiazide diuretic. After 4 weeks of standardised therapy, patients with daytime ambulatory blood pressure of at least 135/85 mm Hg were randomly assigned (1:1) by computer (stratified by centres) to ultrasound renal denervation or a sham procedure. Patients and outcome assessors were masked to randomisation. Addition of antihypertensive medications was allowed if specified blood pressure thresholds were exceeded. The primary endpoint was the change in daytime ambulatory systolic blood pressure at 2 months in the intention-to-treat population. Safety was also assessed in the intention-to-treat population. This study is registered with ClinicalTrials.gov, NCT02649426. **Findings:** Between March 11, 2016, and March 13, 2020, 989 participants were enrolled and 136 were randomly assigned to renal denervation (n=69) or a sham procedure (n=67). Full adherence to the combination medications at 2 months among patients with urine samples was similar in both groups (42 [82%] of 51 in the renal denervation group vs 47 [82%] of 57 in the sham procedure group; p=0.99). Renal denervation reduced daytime ambulatory systolic blood pressure more than the sham procedure (−8.0 mm Hg [IQR −16.4 to 0.0] vs −3.0 mm Hg [−10.3 to 1.8]; median between-group difference −4.5 mm Hg [95% CI −8.5 to −0.3]; adjusted p=0.022); the median between-group difference was −5.8 mm Hg (95% CI −9.7 to −1.6; adjusted p=0.0051) among patients with complete ambulatory blood pressure data. There were no differences in safety outcomes between the two groups. **Interpretation:** Compared with a sham procedure, ultrasound renal denervation reduced blood pressure at 2 months in patients with hypertension resistant to a standardised triple combination pill. If the blood pressure lowering effect and safety of renal denervation are maintained in the long term, renal denervation might be an alternative to the addition of further antihypertensive medications in patients with resistant hypertension. **Funding:** ReCor Medical. © 2021 Elsevier Ltd

Index Keywords

aldosterone antagonist, alpha 1 adrenergic receptor blocking agent, amlodipine, angiotensin receptor antagonist, beta adrenergic receptor blocking agent, calcium channel blocking agent, diuretic agent, hydrochlorothiazide, dmesartan, renin angiotensin system blocker, thiazide diuretic agent, unclassified drug, valsartan, vasodilator agent, angiotensin receptor antagonist, thiazide diuretic agent; adult, age, aged, Article, blood pressure, blood pressure measurement, blood pressure monitoring, clinical effectiveness, clinical outcome, combination drug therapy, controlled study, endovascular ultrasound renal denervation, Europe, female, human, hypertensive patient, intention to treat analysis, kidney denervation, leg edema, major clinical study, male, multicenter study, patient compliance, patient safety, resistant hypertension, single blind procedure, systolic blood pressure, tertiary care center, treatment response, ultrasound, United States, urine sampling, clinical trial, denervation, drug resistance, endovascular surgery, hypertension, innervation, kidney, kidney artery, middle aged, procedures, randomized controlled trial, surgery, ultrasound surgery, vascularization; Angiotensin Receptor Antagonists, Blood Pressure Monitoring, Ambulatory, Calcium Channel Blockers, Denervation, Drug Resistance, Endovascular Procedures, Female, Humans, Hypertension, Kidney, Male, Middle Aged, Renal Artery, Single-Blind Method, Sodium Chloride Symporter Inhibitors, Ultrasonic Surgical Procedures

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