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Systematic Review of Renal Denervation for Uncontrolled Hypertension: Meta-Analysis Results for Office and 24-hour Ambulatory Blood Pressure

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BACKGROUND AND OBJECTIVES

- Uncontrolled hypertension is a leading risk factor for death and cardiovascular complications including stroke, angina, myocardial infarction, heart failure and kidney failure[1].
- Of those diagnosed with hypertension, > 50% of patients treated remain uncontrolled[2].
- Renal denervation (RDN) is a minimally invasive procedure that has been shown to reduce blood pressure and can be considered as a treatment option for uncontrolled, including treatment-resistant hypertension[3 4].
- Previous systematic reviews/meta-analyses (SRs/MAs) have been conducted assessing the efficacy of RDN but differ in their considerations and analyses of trial populations and comparators. Additionally, no published SR or MA have included the most recent pivotal trials (RADIANCE II[5] and SPYRAL HTN-ON MED[6]).

The objective of this systematic review was to assess the efficacy of RDN compared with no RDN or sham control in patients with uncontrolled hypertension, considering the totality of evidence in this field

METHODS

- The SR was conducted using Cochrane and PRISMA guidance, key eligibility criteria is summarised in Figure 1.
- Searches took place in six databases, two trial registers and three HTA/regulatory agency webpages.
- Two independent reviewers assessed the records. Data extraction was conducted by one reviewer, with a second reviewer checking all data points.
- A feasibility assessment was conducted to assess the suitability of the trials for inclusion in the MA.
- The MA used random effects models. Analysis of results at the primary-end point (as reported by the trials) and last follow-up was conducted.

Figure 1: Key eligibility criteria

Population:
Patients aged 18 years or older with uncontrolled hypertension

Intervention:
Radiofrequency or ultrasound, catheter-based RDN

Comparators:
Antihypertensive drug treatment
Sham procedure
Another RDN procedure

Key outcomes:
Change in office/24-hour systolic blood pressure

Study design:
Randomised controlled trials (RCTs) only

RESULTS

Results of the SR and feasibility assessment:

- Searches were conducted between November 2022 and May 2023.
- 6,298 records were found, 25 trials were identified.
- 16 trials were included in the MA:
  - Four “off-med” trials (patients did not receive antihypertensive medication).
  - Twelve “on-med” trials (patients in each arm of the trial received the same regimen of antihypertensive medication).
- Trials where patients received a different regimen in each arm were not included in the MA (n=5). We also did not meta-analyse trials that compared different types of RDN as only two studies were identified.
- Random effects MAs were conducted at the primary endpoint (as reported by the trials), which ranged from 2 – 6 months, and last follow-up, which ranged from 2 – 24 months.

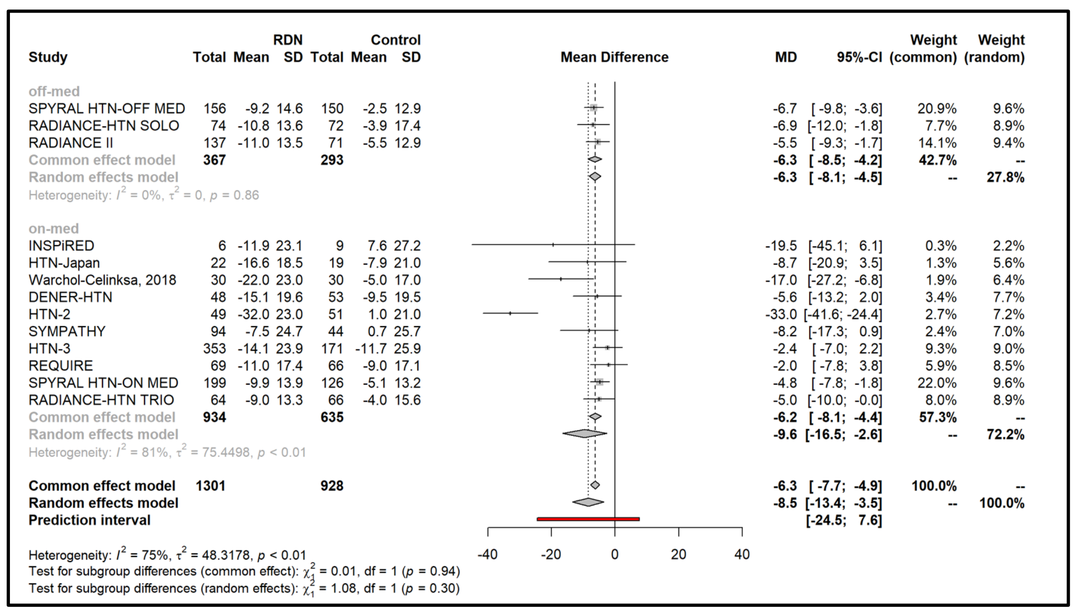
RESULTS (CONTINUED…)

Results of the random effects MAs

- The mean differences and 95% confidence intervals (CIs) for change from baseline in office and ambulatory 24-hour blood pressure for RDN (radiofrequency or ultrasound). compared to control (sham +/- anti-HTN medication or medication alone) at primary and last follow-up are reported below.
- Figure 2 shows the forest plot for change in office systolic blood pressure at primary follow-up.

Office systolic blood pressure (primary follow-up)	Office systolic blood pressure (last follow-up)	Ambulatory 24-hour systolic blood pressure (primary follow-up)	Ambulatory 24-hour systolic blood pressure (last follow-up)
-8.5 (95% CI: -13.4 to -3.5)	**-7.2 (95% CI: -12.5 to -2.0)**	**-3.7 (95% CI: -5.3 to -2.0)**	**-3.3 (95% CI: -5.0 to -1.6)**

Figure 2: Change in office systolic blood pressure at primary follow-up



CONCLUSIONS

- This comprehensive meta-analysis suggests that RDN is effective in achieving clinically meaningful blood pressure reductions in trials where RDN is compared to no RDN or a sham-procedure.

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