

INPLASY PROTOCOL

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Conflicts of interest:
None known.

Effects of renal denervation on cardiac structure and function in heart failure with reduced ejection fraction: a systematic review and meta-analysis

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Review question / Objective: Effects of renal denervation on cardiac structure and function in heart failure with reduced ejection fraction.

Condition being studied: Catheter based renal sympathetic denervation; heart failure with reduced ejection fraction; cardiac structure and function; safety parameters.

Information sources: Studies will be identified by searching PubMed, EMBASE and Cochrane Library until December 2019 and by scanning references of selected studies. For incomplete research, the corresponding author will be contacted for origin data. For the unpublished studies, government websites such as clinical trials, OCLC Papers First, the New York Academy of Medicine, et al. will be searched to find the grey literature. All publications will be restricted to English language papers only.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 May 2020 and was last updated on 03 May 2020 (registration number INPLASY202050009).

INTRODUCTION

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METHODS

Search strategy: Studies were identified by searching PubMed, EMBASE and Cochrane Library until December 2019 and by scanning references of selected studies. The following keywords and Medical Subject Heading were used: 'renal denervation', 'renal sympathetic denervation' and 'heart failure'.

Participant or population: Heart failure with reduced ejection fraction.

Intervention: Patients undergoing catheter based renal sympathetic denervation.

Comparator: Controls are either a control group (e.g. in a randomized controlled trial, patients who received optimal drug therapy or those undergoing a sham operation with or without previous treatment) or the intervention group before the intervention at baseline who act as their own control (e.g. controlled before and after study).

Study designs to be included: Randomized controlled trials, controlled clinical trials, controlled before and after studies, retrospective and prospective cohort.

Eligibility criteria: (1) assessment of the effectiveness of RDN in patients with heart failure who had reduced (<0.50) ejection fraction (EF), (2) controlled or uncontrolled study that provided information on cardiac structure and function, (3) the duration of follow-up was at least 6 months, (4) publication in peer-reviewed journals, English language, reporting baseline and follow-up data regarding the outcomes.

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Main outcome(s): This review will consider studies that include one of the following outcome measures: 1) Effects of RDN on cardiac structure: (e.g. inter ventricular septal thickness (IVST), left ventricular end-diastolic diameter (LVEDD), left ventricular end-systolic diameter (LVESD), left atrial size (LA) et al); 2) Effects of RDN on cardiac function: [e.g. Left ventricular ejection fraction (LVEF), B-type natriuretic peptide (NT-proBNP), heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP) et al]; 3) safety (e.g. renal function, procedural complications such as artery stenosis, artery dissection et al).

Additional outcome(s): Cardiac and cerebral vascular mortality, all-cause mortality, quality of life, hospitalization, et al.

Quality assessment / Risk of bias analysis: To determine the quality of the included studies, we used 1) the Cochrane Collaboration Risk of Bias Tool for the randomized control trials; 2) the Newcastle-Ottawa scale for the observational studies; 3) the Methodological index for non-randomized studies for the non-randomized studies.

Strategy of data synthesis: Effect sizes expressed as odds ratios (for categorical data) and weighted mean differences (for continuous data) and their 95% confidence intervals will be calculated for analysis. Heterogeneity will be assessed statistically using the sensitivity analysis and also explored using subgroup analyses based on the different study designs or follow-up duration included in this review. Where statistical pooling is not possible, the findings will be presented in narrative form.

Subgroup analysis: 1) study type (e.g. RCT vs. observational studies), 2) patient heterogeneity, 3) different duration of follow-up, 4) systolic blood pressure level at baseline. (e.g. Office SBP ≥ 120 mmHg or ≤ 120 mmHg).

Sensibility analysis: Heterogeneity will be assessed statistically using the sensitivity analysis.

Language: English.

Country(ies) involved: China.

Keywords: Renal denervation; heart failure with reduced ejection fraction; cardiac structure and function.

Contributions of each author:

Author 1 - Xuehui Zheng - The author drafted the manuscript.

Author 2 - Xiangping Ma - The author was responsible data extraction and quality assessment.

Author 3 - Yan Qi - The author was responsible data extraction and quality assessment.

Author 4 - Chang Ma - The author provided statistical expertise.

Author 5 - Lingxin Liu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.

Author 6 - Peili Bu - The author read, provided feedback and approved the final manuscript.