INPLASY PROTOCOL

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Lian, Z1.

Review question / Objective: The aim of this meta-analysis is to evaluate the efficacy and safety of catheter-based renal denervation for heart failure with reduced ejection fraction. Condition being studied: Heart failure (HF) affects approximately 23 million people worldwide. Due to its high prevalence and mortality, HF has become a global public health problem. In addition, HF causes a lot of hospitalizations and medical experiences. At present, the treatment of heart failure with RDN is one of the hot spots in clinical research, but the efficiency and safety of RDN are controversial, prompting us to perform a comprehensive meta-analysis of all available evidence on these potential associations.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 June 2020 and was last updated on 19 June 2020 (registration number INPLASY202060071).

INTRODUCTION

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METHODS

Participant or population: Heart failure patients.

Intervention: Catheter-based renal denervation (RDN).

Comparator: Optimal medicine treatment.

Study designs to be included: Selfcontrolled studies, randomized controlled trial (RCT) and cohort trial (CS).

Eligibility criteria: (1) assessment of the efficiency and safety of catheter-based RDN in patients with HF who had reduced ejection fraction (EF), (2) studies that reported at least 1 of the following outcomes: EF, left ventricular end-diastolic diameter (LVEDD), left ventricular endsystolic diameter (LVESD), left atrium diameter (LAD), B-type natriuretic peptide (BNP), N-terminal pro-brain natriuretic peptide levels (NT pro BNP), heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP) and 6minute walk test (6MWT), (3) the duration of follow-up was at least 1 month.

Information sources: Two authors independently searched electronic databases (PubMed, Embase, Web of Science, CNKI, and WanFang).

Main outcome(s): Primary outcomes of interest were EF, LVESD, LVEDD, LAD.

Additional outcome(s): Secondary outcomes of interest were BNP/NT pro BNP level, HR, SBP, DBP and 6MWT.

Quality assessment / Risk of bias analysis: Newcastle-Ottawa Scale (http:// w w w . o h r i . c a / p r o g r a m s / clinical_epidemiology/oxford.asp) was used to assess the quality of the studies.

Strategy of data synthesis: For each outcome, the effect size for the intervention was calculated by the difference between the means of the pre-intervention and postintervention. Furthermore, for randomized controlled trial (RCT) and cohort trial (CS), we calculated the difference between the means of the intervention and control groups at the end of the intervention. If the outcome was measured on the same scale, the weighted mean difference (WMD) and 95% confidence interval (CI) were calculated. Otherwise, the standardized mean difference (SMD) and 95% CI were calculated, continuous variables which were expressed as the mean \pm SD. Heterogeneity between included studies was assessed by I2 statistic, and P < 0.10and I2 > 50% indicated evidence of heterogeneity. If heterogeneity existed among the studies, then the randomeffects model was used. Otherwise, the fixed-effects model was adopted. The potential publication bias was investigated using the funnel plot. The analysis was performed using Review Manager 5.4 and STATA 15.0.

Subgroup analysis: We performed a subgroup analysis based on follow-up time.

Sensibility analysis: The contribution of each included study to the pooled estimate was performed to assess the sensitivity analysis. We use STATA15.0 to analyze the sensibility.

Country(ies) involved: China.

Keywords: heart failure; RDN.

Contributions of each author: Author 1 - Zheng Lian.