INPLASY PROTOCOL

To cite: Zhang et al. His bundle pacing therapy for patients with chronic heart failure: a protocol for meta-analysis based on prospective studies. Inplasy protocol 202110109. doi: 10.37766/inplasy2021.1.0109

Received: 27 January 2021

Published: 28 January 2021

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Support: **None.**

Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None.

His bundle pacing therapy for patients with chronic heart failure: a protocol for meta-analysis based on prospective studies

Zhang, YZ[1]; Ding, MW[2].

Review question / Objective: **To evaluate the effect of his bundle pacing therapy for chronic heart failure.**
Condition being studied: **A considerable amount of studies have been published with the results of clinical benefit from HBP for CHF patients and these researches led a uncertain conclusion for clinics. Thus, we will conduct a meta-analysis to evaluate the effect of his bundle pacing therapy for chronic heart failure.**
Information sources: **Pubmed, EMBASE, the Cochrane Library, Web of Science and Chinese online databases including Chinese National Knowledge Infrastructure(CNKI), China Biology Medicine disc (CBM), Chinese Scientific Journals Database (VIP), and Wanfang Database**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 January 2021 and was last updated on 29 January 2021 (registration number INPLASY202110109).

INTRODUCTION

Review question / Objective: **To evaluate the effect of his bundle pacing therapy for chronic heart failure.**

Condition being studied: **A considerable amount of studies have been published with the results of clinical benefit from HBP for CHF patients and these researches led a uncertain conclusion for clinics. Thus, we will conduct a meta-analysis to evaluate**

the effect of his bundle pacing therapy for chronic heart failure.

METHODS

Participant or population: Chronic heart failure patients.

Intervention: His bundle pacing.

Comparator: Did not accept his bundle pacing.

Study designs to be included: Prospective study, randomized controlled trials.

Eligibility criteria: (1) The subjects were heart failure patients over 18 years old. The patient's nationality, race are not limited in this study. (2) The intervention was his bundle pacing. (3) The outcome measures included: 1) QRS duration; 2) left ventricular ejection fraction; 3) pacing threshold; 4) New York Heart Association (NYHA) classification of cardiac function; 5) left ventricular end-diastolic diameter; 6) left ventricular end -systolic diameter; 7)mitral regurgitation; 8)tricuspid regurgitation; 9)B-type natriuretic peptide (BNP). Among them, 1) and 2) were the primary outcomes, and the rest were secondary outcomes.

Information sources: Pubmed, EMBASE, the Cochrane Library, Web of Science and Chinese online databases including Chinese National Knowledge Infrastructure(CNKI), China Biology Medicine disc (CBM), Chinese Scientific Journals Database (VIP), and Wanfang Database will be searched from these databases construction to the end of November, 2020.

Main outcome(s): 1) QRS duration; 2) left ventricular ejection fraction; 3) pacing threshold; 4) New York Heart Association (NYHA) classification of cardiac function; 5) left ventricular end-diastolic diameter; 6) left ventricular end -systolic diameter; 7)mitral regurgitation; 8)tricuspid regurgitation; 9)B-type natriuretic peptide (BNP).

Additional outcome(s): No.

Data management: No.

Quality assessment / Risk of bias analysis: Two researchers independently evaluated the quality of the included studies. The evaluation tool was the Newcastle-Ottawa scale (NOS). When the total score of NOS in the literature evaluation was ≥ 7, the study was of regarded as high quality. When they have different opinions, the third researcher will assist. After carefully reading the literature, the total score of NOS in the literature will be determined.

Strategy of data synthesis: The STATA 13.0 will be used for data synthesis and meta-analysis. For bivariate data, we use the effect scale index and relative risk ratio of 95% confidence interval (95% CI), whereas the continuous data are represented by mean difference or standardized mean difference and 95% CI. The 95% CI depends on whether the measurement scale is consistent or not. When $P < 0.01$, the data are considered to be statistically significant. $\chi 2$ test and I2 test are used to determine whether there is heterogeneity. If I2 0.1, we can think that there is no heterogeneity in the data analysis, then choose the fixed effect model comprehensive data. If I2 >50%, $P < 0.1$, indicating that there is statistical heterogeneity, the random-effect model is used for analysis. Finally, the subgroup analysis was carried out according to the different causes of heterogeneity. If meta-analysis cannot be performed, a general descriptive analysis can be taken.

Subgroup analysis: If the results are heterogeneous, we will take a subgroup analysis of possible factors that may lead to heterogeneity, such as the sex, age, race, BNP level, NYHA.

Sensitivity analysis: Sensitivity analysis can be carried out when the subgroup analysis is not satisfactory, and it is mainly used to evaluate the robustness of the main results.

Language: English.

Country(ies) involved: China.

Keywords: His bundle pacing, chronic heart failure, meta-analysis, prospective studies.

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