INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Prognostic Value of High-Sensitive C-Reactive Protein in patients with In-Stent Restenosis: A Meta-Analysis of Clinical Trials

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Review question / Objective: **Risk assessment in in-stent restenosis patients is critical in order to provide adequate treatment. In the current meta-analysis, we aim to assess the predictive role of high-sensitive C-reactive protein (hs-CRP) in patients treated with stenting. We searched PubMed, Web of Science, Embase, and Cochrane Registry through May 2022. We selected random control trials that compared the effects of different interventions and revealed the effect of hs-CRP. Two reviewers independently screened articles, extracted data, and assessed the study quality according to the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). Data were pooled using random-effects meta-analysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 May 2022 and was last updated on 31 May 2022 (registration number INPLASY202250170).

INTRODUCTION

Review question / Objective: **Risk assessment in in-stent restenosis patients is critical in order to provide adequate treatment. In the current meta-analysis, we aim to assess the predictive role of high-sensitive C-reactive protein (hs-CRP) in patients treated with stenting. We searched PubMed, Web of Science, Embase, and Cochrane Registry through May 2022. We selected random control trials that compared the effects of different interventions and revealed the effect of hs-CRP. Two reviewers independently screened articles, extracted data, and assessed the study quality according to the PRISMA guidelines (Preferred Reporting Items for Systematic Reviews and Meta-**

Analyses). Data were pooled using random-effects meta-analysis.

Rationale: The occurrence and development of ISR are based on the theory of inflammation and lipids. In addition to anti-inflammatory treatments, many studies have paid attention to the diagnostic and predictive value of inflammatory markers for ISR. high-sensitivity C-reactive protein (hs-CRP), like C-reactive protein, is an inflammatory protein, but not the same kind. hs-CRP is characterized by a more sensitive test method and reflects a persistent chronic inflammatory state. There is a high level of concern among the risk factors for inflammation biomarkers. Some previous studies have pointed out that hs-CRP is an independent risk factor for ISR, but some studies have reached the opposite conclusion. By way of illustration, we show that baseline hs-CRP did not indicate more severe vascular lumen loss. Previous systematic reviews pointed out that hs-CRP's positive predictive value of ISR. This system review, however, has several flaws. Firstly, this result was entirely conducted by retrospective studies. Secondly, neither the age nor the diabetes was adjusted in the subgroup. Finally, the hs-CRP level at baseline and follow-up was not adequately analyzed. Therefore, in this contradictory situation, we re-examined the literature based on randomized controlled clinical trials (or prospective cohort studies specifically evaluating the diagnostic value of hs-CRP) to assess the diagnostic prediction value of hs-CRP in patients undergoing stenting.Many studies have paid attention to the diagnostic and predictive value of inflammatory markers for ISR. Some previous studies have pointed out that hs-CRP is an independent risk factor for ISR, however, this result was entirely conducted by retrospective studies. Secondly, neither the age nor the diabetes was adjusted in the subgroup. Finally, the hs-CRP level at baseline and follow-up was not adequately analyzed.

Condition being studied: Studies were included if they met the following criteria: used a well-defined randomized controlled design or cohort design; clearly stated that hs-CRP was one of the main exposure factors for ISR in patients undergoing PCI, and provided a 95% confidence interval (CI) for Odds ratios (ORs) for mortality or reported case data for the intervention and control groups were used to calculate these parameters.

METHODS

Search strategy: PubMed, Web of Science, Embase and Cochrane databases to identify relevant studies published as of March 2022. The search keywords were "percutaneous coronary intervention", "in-stent restenosis" and "high-sensitivity C-reactive protein". Post-search literature was screened and references of included studies were manually searched for additional relevant publications. Search stratedy in Pubmed:((((((((((("Percutaneous Coronary Intervention"[Mesh]) OR (Coronary Intervention, Percutaneous[Title/Abstract])) OR (Coronary Interventions, Percutaneous[Title/Abstract])) OR (Intervention, Percutaneous Coronary[Title/Abstract])) OR (Interventions, Percutaneous Coronary[Title/Abstract])) OR (Percutaneous Coronary Revascularization[Title/Abstract])) OR (Coronary Revascularization, Percutaneous[Title/Abstract])) OR (Coronary Revascularizations, Percutaneous[Title/Abstract])) OR (Percutaneous Coronary Revascularizations[Title/Abstract])) OR (Revascularization, Percutaneous Coronary[Title/Abstract])) OR (Revascularizations, Percutaneous Coronary[Title/Abstract])) OR ((((((("Stents"[Mesh]) OR (Drug Eluting Stents[Title/Abstract])) OR (Stents[Title/Abstract])) OR (stent[Title/Abstract])) OR (stenting[Title/Abstract])) OR (Bare Mental Stents[Title/Abstract]))) AND (((((("C-Reactive Protein"[Mesh]) OR (hsCRP[Title/Abstract])) OR (High Sensitivity C-Reactive Protein[Title/Abstract])) OR (High Sensitivity C Reactive Protein[Title/Abstract])) OR (hs-CRP[Title/Abstract])).

Participant or population: Patients undergoing PCI.

Intervention: Oral anti-inflammations or Drug eluting stents.

Comparator: Placebo or Bare mental stents.

Study designs to be included: RCT or prospective cohort.

Eligibility criteria: The literature that cannot obtain the full text and effective information will be removed.

Information sources: PubMed, Embase, Scopus, Cochrane Central Register of Controlled Trials, Clinical trials. gov, Wan fang Data (Chinese), VIP (Chinese), and CNKI (Chinese).

Main outcome(s): In-stent restenosis

Additional outcome(s): None.

Data management: Data from the included articles were independently extracted by the first two authors using a predefined standardized electronic extraction file based on the CHARMS-PF checklist. The following characteristics were extracted from each article: study design, number of participants, age, sex, BMI, NYHA class, WHO classification, treatment type, follow-up duration, type of biomarker, (NT-pro-)BNP levels, renal function, analyzing assay, cut-off values, and HR with accompanying 95% confidence intervals. Corresponding authors were contacted when the univariable or multivariable HR were not reported. Studies were excluded if additional information could not be provided.

Quality assessment / Risk of bias analysis: All included full-text articles underwent rigorous study quality assessment using the Revman tool. We assessed 1) Random sequence generation, 2) Allocation concealment, 3) Blinding of participants and personal, 4) Blinding of outcome assessment, 5) Incomplete outcome data, 6) Selective reporting, and 7) Other sources of bias.

Strategy of data synthesis: Pooled analyses were carried out at any follow-up point by RevMan 5.3 software (Copenhagen: The Nordic Cochrane Center, The Cochrane Collaboration, 2014).

Subgroup analysis: Subgroup analyses were conducted based on different ages, hs-CRP levels (< 1 month vs 6-12 months), and diabetes.

Sensitivity analysis: Sensitivity analyses were conducted to confirm the stability of the conclusion.

Language: English.

Country(ies) involved: China.

Keywords: High-Sensitive C-Reactive Protein, In-Stent Restenosis

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