INPLASY PROTOCOL

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Risk factors and Prevalence of Diabetic Retinopathy: A Protocol for Meta-analysis

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The authors have no conflicts of interest to disclose.

Review question / Objective: **Relationship between risk factors and incidence of diabetic eye disease.**
Condition being studied: **Diabetic retinopathy (DR) is one of the serious complications of diabetes mellitus. Without further treatment, it can evolve into the stage of proliferation, which will lead to the formation of new blood vessels, vitreous hemorrhage or anterior retinal hemorrhage, which will lead to severe vision loss and increase the risk of blindness.**
Information sources: **"Diabetic retinopathy" was used as the English search term, database retrieval was carried out on MEDLINE, Embase, ovid, Web of Science, Wanfang, CNKI database, and literatures on diabetic retinopathy published from the establishment of the database to July 2019 were collected systematically**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 23 July 2020 and was last updated on 23 July 2020 (registration number INPLASY202070107).

INTRODUCTION

Review question / Objective: **Relationship between risk factors and incidence of diabetic eye disease.**

Condition being studied: **Diabetic retinopathy (DR) is one of the serious complications of diabetes mellitus. Without further treatment, it can evolve into the stage of proliferation, which will lead to the formation of new blood vessels, vitreous**

hemorrhage or anterior retinal hemorrhage, which will lead to severe vision loss and increase the risk of blindness.

METHODS

Participant or population: Diabetic retinopathy.

Intervention: Not application.

Comparator: Not application.

Study designs to be included: (1) Randomized controlled trial; (2) cohort studies; (3) case-control studies.

Eligibility criteria: Advanced age, male gender, DM duration, insulin treatment, fasting blood glucose [FBG], 2-hour postprandial blood glucose [2h-PBG], glycated haemoglobin A1c [HbA1c], total cholesterol [TC], triglyceride [TG], body mass index [BMI], systolic blood pressure [SBP].

Information sources: "Diabetic retinopathy" was used as the English search term, database retrieval was carried out on MEDLINE, Embase, ovid, Web of Science, Wanfang, CNKI database, and literatures on diabetic retinopathy published from the establishment of the database to July 2019 were collected systematically.

Main outcome(s): Incidence of diabetic retinopathy.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of included studies by using the Newcastle-Ottawa Scale (NOS) for nonrandomized studies.19,20 This is a specific method for assessing the quality of cohort and case-control study. There are 8 entries in 3 modules, among which 4 points are selected for study population, 2 points for comparability between groups, and 3 points for measurement of results. The total score ≥6 points is considered as high-quality research literature. The Cochrane bias risk assessment tool was used to evaluate the final included RCTs: random allocation method; allocation plan concealment; blinding of research subjects and experimenters; blinding of outcome evaluators; completeness of result data; selective reporting of studies Results; other sources of bias, including potential bias related to the specific research design of the study.21 For each of the above items, make a judgment of "low risk of bias", "high risk of bias" and "uncertain risk of bias". Disagreement will be solved by discussion or by consulting the third person (SLS).

Strategy of data synthesis: Statistical analysis was performed on the extracted data using Stata 12.0 software. For measurement data, the weighted mean difference (WMD) is used as the combined effect size; for binary variable data, the odds ratio (OR) is used as the combined effect size. Use the statistics I2 and P values to test the heterogeneity of the combined literature. If $P \geq 0.1$, $I2 < 50\%$, it indicates that there is homogeneity among the studies or the heterogeneity is within the acceptable range, and the fixed effects model is used to merge the calculation of the effect size; on the contrary, it is considered that there is heterogeneity between the studies. Egger's method and begg's method were used to assess publication bias.

Subgroup analysis: If the evidence is sufficient, we will conduct a subgroup analysis to determine the difference between different gender, age (Over 60 years old, less than 60 years old) etc.

Sensibility analysis: Sensitivity analysis was performed according to different sample sizes.

Country(ies) involved: China.

Keywords: Diabetic retinopathy, risk factors; meta-analysis.

Contributions of each author:
Author 1 - Yuying Hou - Yuying Hou is responsible for the following contents: conceptualization, methodology, software, writing – original draft, writing – review and editing.

Author 2 - Yitong Cai - Yitong Cai is responsible for the methodology.
Author 3 - Zhumin Jia - Yuying Hou is responsible for the following contents: software, writing – original draft, writing – review and editing.
Author 4 - Suling Shi - Suling Shi is responsible for the following contents: software, writing – original draft, writing – review and editing.