INPLASY PROTOCOL

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Corresponding author:
Longqian Liu

b.q15651@hotmail.com

Author Affiliation:
West China Hospital, Sichuan University

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Conflicts of interest:
None.

Choroidal vascular changes in age-related macular degeneration: a protocol for systematic review and meta-analysis

Wang, X[1]; Zeng, L[2]; Chen, M[3]; Liu, L[4].

Review question / Objective: **The purpose of the study is to evaluate choroidal structural alternations measured by CVI in AMD.**
Condition being studied: **Age-related macular degeneration (AMD), as an increasing age-related eye disease, is becoming a leading cause of irreversible visual impairment and blindness in elder population.The mechanism of AMD remains uncertain and covers a complex risk factors. Advances in swept-source OCT with enhanced depth imaging (EDI) model make a more detailed study of choroid and accurate assessment of the potential effect of choroid in the pathogenic mechanism of AMD. Choroidal vascularity index (CVI) is a sensitive parameter obtained by enhanced depth imaging of optical coherence tomography which allows the choroid in more detail and accurate assessment in the pathogenesis of AMD.Previous studies have investigated that the CVI is reduced in AMD patients, with no difference between early stage and late stage of AMD. Similarly, there is no significant difference in CVI between neovascular AMD and PCV obtained by two studie. CVI is also significantly diminished in AMD with geographic atrophy. Otherwise, increased CVI was noted in wet AMD with activation of CNV and in PCV with choroidal vascular hyperpermeability. At present, the change of CVI in AMD remains unclear. However, to the best of our knowledge, no meta analysis has performed on this subject.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 October 2020 and was last updated on 12 October 2020 (registration number INPLASY2020100041).

INTRODUCTION

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increasing age-related eye disease, is becoming a leading cause of irreversible visual impairment and blindness in elder population.The mechanism of AMD remains uncertain and covers a complex risk factors. Advances in swept-source OCT with enhanced depth imaging (EDI) model make a more detailed study of choroid and accurate assessment of the potential effect of choroid in the pathogenic mechanism of AMD. Choroidal vascularity index (CVI) is a sensitive parameter obtained by enhanced depth imaging of optical coherence tomography which allows the choroid in more detail and accurate assessment in the pathogenesis of AMD.Previous studies have investigated that the CVI is reduced in AMD patients, with no difference between early stage and late stage of AMD. Similarly, there is no significant difference in CVI between neovascular AMD and PCV obtained by two studie. CVI is also significantly diminished in AMD with geographic atrophy. Otherwise, increased CVI was noted in wet AMD with activation of CNV and in PCV with choroidal vascular hyperpermeability. At present, the change of CVI in AMD remains unclear. However, to the best of our knowledge, no meta analysis has performed on this subject.

METHODS

Search strategy: We will search the databases of PubMed, Embase, the Cochrane library, and Web of Science from their inception until present. The primary search strategies are: ("optical coherence tomography" OR "choroidal vascularity index" OR "Choroid") AND "age-related macular degeneration" OR "choroidal vascularity index". Additionally, relevant studies from the reference lists will be also manual-searched and examined for retrieved studies.

Participant or population: We will accept any clinically diagnosed criteria of AMD regardless of age, race, and gender.

Intervention: We will only include studies that use OCT to assess the choroidal vascular changes in patients with AMD on CVI. The control group will consist of healthy eyes in the absence of any eye diseases especially choroidal retinopathy.

Comparator: Health controls.

Study designs to be included: We will consider case-control studies using OCT scans to obtain the CVI in AMD and healthy controls.

Eligibility criteria: All articles in English were considered eligible. However, studies with insufficient data, animal experiment, abstracts, letters, reviews, editorials, and case-reports will be excluded.

Information sources: Four databases (PubMed, Embase, the Cochrane library, and Web of Science) will be searched from their inception until present.

Main outcome(s): The primary outcome is the change of CVI between AMD and the controls.

Quality assessment / Risk of bias analysis: Newcastle-Ottawa Scale (NOS) will be applied to evaluate the risk of bias assessment for each eligible study which includes eight assessment indicators: selection (4 items), comparability (1 item), and outcome (3 items)[29]. The total scores ranging from 0 to 9 points apply to the evaluation and results will be presented on a table. Studies with NOS scores > 7 will be defined as high quality and consider in the final analysis.

Strategy of data synthesis: Statistical analysis will be conducted using RevMan 5.3 software. For continuous variables, outcomes will be reported as the mean ± standard deviation (SD) and the mean difference (MD) with a 95% confidence interval (CI). To obtain reliable results, heterogeneity will be evaluated using the I2 test. If the homogeneity test shows $P \geq 0.1$ and $I2 \leq 50\%$, which indicates a low homogeneity between the included studies, a fixed-effects model will be utilized to pool the data. If the value of I2 is > 50% or P value < 0.1, which means a high heterogeneity, then a random-effects

model will be applied to pool the data. Meanwhile, subgroup analysis will be performed to explore the possible causes. A P value <0.05 is defined as statistically significant.

Subgroup analysis: If there is apparent clinical heterogeneity and sufficient data, subgroup analysis will be conducted based on patient characteristics and OCT device brand such as duration of AMD, subtype of AMD and so on. However, if significant heterogeneity is still identified after subgroup analysis, then data will not be recommended to pool, and meta-analysis will not be performed. Instead, a narrative summary will be reported ultimately.

Sensibility analysis: We will carry out sensitivity analysis to check the robustness of the pooled outcome data.

Language: English.

Country(ies) involved: China.

Keywords: Age-related macular degeneration, choroidal thickness, choroidal vascularity index, optical coherence tomography.

Contributions of each author:
Author 1 - Xiaoqin Wang - The author contributed to conception, design, data analysis, and writing original draft.
Author 2 - Liuzhi Zeng - The author provided soft analysis guidance and revision of the manuscript.
Author 3 - Ming Chen - The author provided methodological support and data extraction.
Author 4 - LongQian Liu - The author contributed to the editing and revision of the manuscript.