Study Protocol

Test accuracy of OCT and OCT-A for the diagnosis of myopic choroidal neovascularisation: A systematic review and meta-analysis

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BACKGROUND

The present study aims to determine the test accuracy of optical coherence tomography (OCT) and/or OCT-angiography (OCT-A) in diagnosing myopic choroidal neovascularisation compared to the reference standard, fluorescein angiography.

METHODS

This systematic review and meta-analysis will be conducted and reported in compliance with established methodological guidelines.[1,2] Study selection, evidence appraisal and data abstraction will be undertaken by at least two authors. Disagreements will be settled by obtaining the opinion of a third author. Majority decisions will prevail.

Literature search

MEDLINE (www.PubMed.org) and EMBASE (www.EMBASE.com) will be searched using appropriate MeSH and Emtree terms to identify the main topics of interest and these key terms will be crossed with search strategies optimised to detect studies of diagnostic accuracy.[3-5] Complete search strategy details will be reported in the Online Supplement at time of manuscript publication. We will not use any language restrictions in the electronic searches. Reference lists of retrieved primary studies and review articles will be hand searched. Close out date of the electronic search will be reported in the main manuscript.

Study selection

All studies evaluating the test accuracy of OCT and/or OCT-A against a reference standard in diagnosing myopic choroidal neovascularisation will be retrieved and screened for inclusion. We will include any combination of OCT and/or OCT-A model assessed against the reference standard fluorescein angiography.[6] Exclusion criteria will be case reports, review articles, non-human studies and any article type where primary data to calculate sensitivity and specificity against the reference standard is unavailable.

Framing clinical recommendations

The GRADE guidelines for assessing certainty of the evidence with respect to study design, and the domains of risk of bias, indirectness, imprecision, inconsistency and publication bias will be used to frame clinical recommendations.[1,2] The GRADE assessment framework is supported by published reporting guidelines including PRISMA-Diagnostic Test Accuracy and Cochrane.[7-11]

Risk of bias

All included studies will be appraised using the QUADAS-2 tool[12] for risk of bias and applicability, which covers patient selection, index test, reference test, and flow and timing. Studies will be rated "high", "low" or "unclear" for risk of bias, and results graphed using a 'traffic light system' as

proposed in the GRADE guidelines.[1] The "unclear" category will be used only when insufficient data are reported to permit a judgment.

Outcomes

The primary outcome of interest is test accuracy. Downstream consequences (e.g. management decisions, health outcomes, resource utilisation)[13] will be investigated as secondary outcomes.

Analysis

Given the limitations of all the available statistical models and methods to test for publication bias in test accuracy studies, and lack of a standardized method to register test accuracy studies,[2] we will assess publication bias using Deeks' test[14] provided ten or more studies are identified.

Pooled estimates (with 95% confidence intervals) of sensitivity and specificity for each index test (OCT/OCT-A) will be obtained using a bivariate model. Study differences in patient populations, patient selection, risk of bias, clinical setting, disease severity, scan density, scan quality and retinal thickness will be explored as sources of heterogeneity.

Stable pooled estimates of sensitivity and specificity will be used to 'back-calculate' estimates of positive likelihood ratio, negative likelihood ratio, positive predictive value and negative predictive value for each index test.

All statistical analyses will be conducted using RevMan 5.4.1 (The Cochrane Collaboration®, Oxford, England, 2020), and the SAS macro MetaDAS v1.3.

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