BMJ Open

Two-field non-mydriatic fundus photography for diabetic retinopathy screening: a protocol for a systematic review and meta-analysis

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To cite: Yu D, Dou X, Chen J, *et al*. Two-field non-mydriatic fundus photography for diabetic retinopathy screening: a protocol for a systematic review and meta-analysis. *BMJ Open* 2021;**11**:e051761. doi:10.1136/bmjopen-2021-051761

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-051761).

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Received 31 March 2021
Accepted 23 September 2021

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ABSTRACT

Introduction Diabetic retinopathy (DR) is one of the most prevalent microvascular complications of diabetes mellitus. Guidelines for DR screening in different countries vary greatly, including fundus photography, slit-lamp biomicroscopy, indirect ophthalmoscopy, Optical Coherence Tomography (OCT), OCT-A and Fundus Fluorescein Angiography (FFA). Two-field non-mydriatic fundus photography (NMFP) is an effective screening method due to its low cost and less time-consuming process. However, it is controversial due to the sensitivity and specificity of two-field NMFP. This review intends to evaluate the performance of the two-field NMFP in diagnosing DR and helps clinicians determine the most optimal screening method.

Methods and analysis Two reviewers will independently search on the Medline, Embase, Cochrane databases, ProQuest, Opengrey, Chinese National Knowledge Infrastructure, Wanfang Data, VIP China Science and Technology Journal Database, Chinese BioMedical Literature Database, ISRCTN, ClinicalTrials.gov and the WHO ICTRP to identify relevant studies. There is no restriction posed on the language of the study. Included studies focus on the performance of two-field NMFP in detecting DR in diabetes patients. Analysis and evaluation of the studies will be examined by two reviewers independently using the Quality Assessment for Diagnostic Accuracy Studies-2 tool and later evaluated using the Population, Intervention, Comparison, Outcome, Study design criteria. A random-effect model will calculate the diagnostic indicators, including the sensitivity, specificity, positive likelihood ratio, negative likelihood ratio, diagnostic OR, area under the curve and 95% CIs. We will also develop a summary receiver operating characteristic curve. We anticipate analysing subgroups according to the factors, which may lead to heterogeneity, including DR levels of patients, the reference standards, camera models, the interpretation criteria. The data will be analysed by STATA software. This study was registered with PROSPERO.

Ethics and dissemination This review will analyse the published data. Patients/the public were not involved in this research. The results of this study will be published in peer-reviewed journals.

PROSPERO registration number CRD42020203608.

Strengths and limitations of this study

- This study may provide the most appropriate screening methods and reliable, evidence-based medicine for diabetic retinopathy (DR).
- The heterogeneity has multiple sources, including different DR levels of patients imaged, the imaging procedure, the reference standards, camera models, ungradable images, the experience of the ophthalmologist, the interpretation criteria or a combination of these factors.
- All of the included studies used diagnostic case–control designs.
- Findings of the proposed systematic review and meta-analysis may be limited by publication bias, study heterogeneity and the methodological quality of existing research.
- We cannot guarantee that all relevant studies will be included in this meta-analysis.

INTRODUCTION

Diabetic retinopathy (DR) is one of the chronic complications of diabetes that causes cases of blindness among the working population.[1 2] Blindness due to DR is one of the most feared complications and one of the most preventable.[3 4] According to Global Vision Database, regarding the pooled rate of 14 global WHO study centres, about 3.2 million patients with DR were estimated to suffer from moderate or severe vision impairment by 2020.[5]

Rationale

Early DR develops relatively slowly; thus, the vision-threatening DR usually develops several years after the diagnosis of diabetes .[6] With a high prevalence of DR, early detection and treatment of DR are necessary for the diabetic population due to the poor prognosis of late DR. Early treatment can prevent 90% of severe vision loss.[7] Blindness was also

Table 1 Representative guidelines of DR screening guidelines in different countries

Guidelines	Country	Screening methods	Ref
2020 AAO	USA	Slit-lamp biomicroscopy and indirect ophthalmoscopy	12
2017 AAO	USA	Dilated comprehensive eye exam or retinal photography	28
2016 UK NSC	UK	Digital photography	29
2012 RCOphth	UK	Digital photography (but selective mydriasis and numbers of fields are controversial)	30
2018 Denmark	Denmark	Fundus photography or mydriatic with at least two fields	31
2017 SED/SEV	Spain	Non-mydriatic retinopathy or mydriatic retinopathy	32
2012 COS	Canada	Slit-lamp biomicroscopy and 7SF	33
2016 NZ	New Zealand	Pupil dilation or colour digital retinal photography and slit-lamp biomicroscopy	34
2018 Poland	Poland	Ophthalmoscope with mydriasis by an ophthalmologist or fundus camera by trained personnel	35
2017 China	China	Two-field fundus photography (45–65 degrees)	36

DR, diabetic retinopathy; 7SF, 7-standard-field stereoscopic colour retinal imaging.

reduced significantly in Iceland, England and Wales through DR screening programs.[8–11] However, 43%–65% of diabetic patients have not received a fundus examination when seeing a doctor. The fundus examinations promptly detect the vision-threatening symptoms of DR. Therefore, early prevention can be applied.

Multiple screening techniques can detect and classify DR. Guidelines for DR screening in different countries vary greatly. Although several other countries have screening guidelines, we choose several representative guidelines to show that the screening techniques vary greatly in different countries in table 1. These stated guidelines show the divergent screening methods used in few countries. Not all the guidelines available are listed in the table. The latest published guideline by the American Academy of Ophthalmology in 2020 suggested using slit-lamp biomicroscopy and indirect ophthalmoscopy on DR detection.[12] The UK National Screening Committee guideline established in 2016 sets up an adult screening programme for DR, while photographs of the back of the eyes are being used for diagnosis.

The 7-standard-field stereoscopic colour retinal imaging (7SF) is referred to as the gold standard in considerable research. Correspondingly, the Early Treatment Diabetic Retinopathy Study has used 7SF as the reference standard.[13] Ophthalmologic slit-lamp biomicroscopy is also a commonly used detection method with high accuracy. Scanlon *et al* concluded that slit-lamp biomicroscopy by an ophthalmologist is a competitive method compared with 7SF for DR detection.[14] However, these methods are too complex and tedious for primary care screening. Therefore, an effective and cost-efficient screening and detection strategy broadly accepted for DR is required.

Two-field non-mydriatic retinopathy is one of the cost-efficient screening and detection strategies on DR.[15] Most accessible reviews evaluated the accuracy of several DR screening methods inclusively. For instance, Piyasena *et al* evaluated the DR test accuracy of two-field mydriatic retinopathy and two-field non-mydriatic fundus photography (NMFP).[16] They examined the DR test accuracy by composing different combinations of the number of retinal fields, index test graders, pupil status and any possible confounding factors that might affect DR screening accuracy. However, only four studies of two-field NMFP were included in this analysis. Likewise, Bragge *et al* published a meta-analysis examining the effect of mydriasis and medical qualifications of photographers on the accuracy of DR screening.[17] A systematic and comprehensive up-to-date analysis is required to address how effective the two-field NMFP is in diagnosing DR. Our meta-analysis aims to evaluate the non-mydriatic, two-field retinopathy exclusively regarding its accuracy and performance.

Pharmacological mydriasis usually results in blurred vision lasting several hours. Even though mydriasis significantly improves the technical failure rate of retinal photography, most patients refrain from doing eye examinations for DR screening. Because after mydriasis, they would not be able to work, drive or walk without assistance. Thus, undilated fundus photography is consequently favoured for screening.

Single-field NMFP is considered the simplest screening method in the primary care setting, but it did not meet the British Diabetic Association (BDA) standard according to our previous meta-analysis study.[18] According to BDA, the screening method for DR needs to achieve at least 80% sensitivity and 95% specificity.[19] Admittedly, sufficient studies proved that single-field NMFP does not have the required sensitivity and specificity. Two-field NMFP is being studied and evaluated as to whether it is an effective screening method in certain research. However, it is controversial as far as the sensitivity and specificity of two-field NMFP are concerned. Saari *et al* reported that the sensitivity (88.9%) and specificity (100%) of two-field NMFP met the technical requirements of BDA.[20] But Boucher *et al* and Perrier *et al* reported the sensitivity (97.7%, 95.7%, respectively) and specificity (84.0%, 75.8%, respectively).[21 22] The specificity of two-field

NMFP in these studies did not meet the BDA standard of more than 95% specificity. Furthermore, the different performances of two-field NMFP for DR detection evoked much controversy. Previous systematic reviews and meta-analyses include only four studies with limited samples. Thus, there is an urgent need to determine whether it is an effective screening strategy through an up-to-date systematic review and meta-analysis.

Objective

This study aims to evaluate the effectiveness of two-field NMFP in DR detection by performing a meta-analysis. The main objective of the systematic review purposes is to facilitate physicians in determining the most appropriate screening tool for DR.

METHODS AND ANALYSIS

The systematic review and meta-analysis will be prepared according to a prespecified protocol registered with PROSPERO (without peer review) for the Preferred reporting items for systematic review and meta-analysis protocols 2015 statement.[23]

Inclusion criteria

Two reviewers will independently examine all the acquired studies and evaluate them using the information provided in the title and abstract. The studies will be eligible for this study only if they met the following PICOS criteria (table 2): (1) Population (P), type 1 or/and type 2 diabetes patients known or suspected to have any level of DR; (2) Intervention (I), two-field NMFP focusing on two centres as a screening method for DR, photographs are graded by ophthalmologists and provided with the original data; (3) Comparison (C), standard diagnostic methods (eg, 7SF, slit-lamp biomicroscopy, FFA); (4) Outcome (O), diagnostic accuracy of Two-Field NMFP for DR, using 7SF or slit-lamp biomicroscopy as the reference standard; (5) Study design (S), prospective case–control studies. The study setting includes all kinds of settings, for example, major hospitals, primary care settings, etc.

Table 2 PICOS criteria for this study

PICOS	Description
Population (P)	Patients known or suspected to have DR
Intervention (I)	Two-field NMFP as a screening method for diabetic retinopathy
Comparison (C)	Standard diagnostic methods (7SF, slit-lamp biomicroscopy, FFA)
Outcome (O)	Diagnostic accuracy of two-field NMFP for DR, using 7SF or slit-lamp biomicroscopy as the reference standard
Study design (S)	Prospective case–control studies

DR, diabetic retinopathy; NMFP, non-mydriatic fundus photography; 7SF, 7-standard-field stereoscopic colour retinal imaging.

Literature search

Two reviewers (DY and LM) independently screened all the acquired studies based on the title and abstract information. After that, the full text of the selected articles will be evaluated for eligibility. The consensus of the two reviewers will resolve any discrepancy.

We will search the Medline Ovid, Embase Ovid, Cochrane databases, ProQuest, Opengrey, Chinese National Knowledge Infrastructure (CNKI), Wanfang Data, VIP China Science and Technology Journal Database (VIP), Chinese BioMedical Literature Database (CBM), ISRCTN, ClinicalTrials.gov and the WHO ICTRP to identify studies updated to the time we search. There will be no restriction based on language. In addition, we will use a combination of medical subject headings and text terminologies to define the study population (people with diabetes), the pathological process of interest (DR) and the specific screening techniques used (fundus photography or digital retinal imaging system). The duplicates will be removed, and each article is screened based on its title and abstract. Subsequently, we will assess the full text of studies and include only relevant studies in our meta-analysis. The search strategy was described in online supplemental file S1. We will also examine the reference lists in articles to obtain additional studies not obtained by the electronic search.

Quality assessment

Two reviewers (DY and LM) will independently assess the quality of the selected studies using the Quality Assessment for Diagnostic Accuracy Studies (QUADAS-2).[24] QUADAS-2 intends to assess the quality of primary diagnostic accuracy studies by evaluating the risk of bias and applicability in patient selection, the index test, and the reference standard will be used for study flow and timing. We will then use these assessments to evaluate the risk of bias of all the included studies: (1) low, if there are no risks of bias in four key domains; (2) unclear, if there is not enough information provided for the assessment of the risk of bias; (3) high, if the risk of bias is high for one or more key domains. Disagreements will be discussed with a third reviewer and will be further resolved by consensus.

Data extraction

Two reviewers (DY and LM) will extract the characteristics independently from the included studies, including (1) true positives, (2) false positives, (3) true negatives, (4) false negatives, (5) sampling method, (6) sample size, (7) country, (8) age, (9) gender, (10) diabetes type, (11) duration of disease, (12) camera model, (13) reference test into an Excel sheet. Disagreements and discrepancies will be discussed with a third reviewer and resolved by consensus. The search and data extraction will be done in 6 months after this protocol is accepted. The data will be extracted into an Excel sheet.

Data analysis

The data synthesis and analysis evaluate the diagnostic performance and accuracy of the two-field NMFP in

detecting any DR. We will analyse data for eyes, but ungradable images will be excluded. The statistical analysis will be performed by STATA V.16.0. We will calculate the following outcome: sensitivity, specificity, positive likelihood ratio, negative likelihood ratio and the diagnostic OR with 95% CIs. If high heterogeneity is induced, we will likely use the random-effects model as opposed to a fixed-effect model to assess the statistical heterogeneity among all included studies. Consecutively, we will consider the I^2 statistic to evaluate the heterogeneity in all the studies. In general, a higher percentage of I^2 indicates increasing heterogeneity. Moreover, I^2 >50% (p=0.05) will be considered statistical heterogeneity.[25] Besides, we will perform the receiver-operating characteristic (ROC) curves and use the sensitivity, specificity and area under the curve to facilitate statistical analysis.[26] If there are more than ten studies are included, we will take the summary operating point on the summary ROC (SROC) curve as the estimate of the test performance among all studies in our meta-analysis. Thus, we will extrapolate the Q values, when specificity equals sensitivity on the SROC curve, to further evaluate heterogeneity. Funnel plots will be used to visualise publication bias in meta-analysis. We will plot on a logarithm scale using SE and the effect measure. Moreover, the heterogeneity in all studies will be considered in the analysis. We anticipate analysing subgroups according to the factors potentially leading to heterogeneity, including different DR levels of patients imaged, the imaging procedure, the reference standards (eg, 7SF, slit-lamp biomicroscopy, FFA), camera models, ungradable images, the experience of the ophthalmologist, the interpretation criteria. If a high degree of heterogeneity occurs, we will present the findings narratively.

Patient and public involvement

Patients were not involved in the design of this study.

Ethics and dissemination

Since we will not collect primary data of individual patients, there is no need for ethical approval. The final results of this analysis will be published in a peer-reviewed journal. It will provide evidence of accuracy on two-field NMFP to the ophthalmologists or any healthcare workers in the primary clinic setting.

Amendments

The protocol for this study will be amended if new guidelines for DR screening are released during preparation.

DISCUSSION

It remains controversial whether two-field NMFP is efficient enough to be a DR screening method according to BDA standard.[22 27] DR and its levels were crucial for clinical studies to make therapeutic methods and avoid further progression. Therefore, this meta-analysis aims to collate comprehensive, up-to-date evidence concerning the diagnostic test accuracy of two-field NMFP for DR detection, to answer whether two-field NMFP is efficient enough to be a DR screening method, according to BDA standards.

The results may have important practical implications for clinicians, patients with DR and those working on DR research. Our findings will also be expected to provide evidence for clinical decision support for DR screening. It can also guide the DR screening method for healthcare professionals. To this end, the results of this systematic review and meta-analysis will be published in a peer-reviewed journal, potentially benefitting healthcare professionals, patients and guideline makers.

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Contributors ZP conceived the idea, planned, conceived and designed the protocol. LM designed and piloted the search strategy. DY, XD, JC, YL, ZW, XH, XT, BZ, YD, WL, BY, XW, QL critically reviewed and provided feedback. LM and DY wrote the manuscript. XD, BY, XW and LM revised the manuscript. ZP and LM are the guarantors of the review.

Funding This work was supported by Shenzhen High-level Hospital Construction Fund (2019), grant number not applicable, Clinical Research Project of Shenzhen Second People's Hospital (grant number: 20193357009).

Competing interests None declared.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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