INPLASY

Diagnostic Accuracy of Eye Art for Fundus-Based Detection of Diabetic Retinopathy: A Systematic Review and Meta-analysis

INPLASY202550079

doi: 10.37766/inplasy2025.5.0079

Received: 26 May 2025

Published: 26 May 2025

Corresponding author:
Ting Wei Wang

twang180@jh.edu

Author Affiliation:
National Yang-Ming Chiao Tung University.

Wang, TW; Luo, WT; Tu, YK; Chou, YB; Wu, YT.

ADMINISTRATIVE INFORMATION

Support - NR.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202550079

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 May 2025 and was last updated on 26 May 2025.

INTRODUCTION

Review question / Objective Using the PICOS framework: P – adults (≥18 y) undergoing retinal screening; I – EyeArt v2.1 autonomous AI applied to 1, 2-field or more-field color fundus photographs; C – expert dilated fundus examination or masked human grading of images (reference standard); O – diagnostic accuracy for referable diabetic retinopathy (rDR) expressed as sensitivity, specificity, likelihood ratios, and post-test probabilities; S – prospective or retrospective diagnostic-accuracy studies. Objective: To quantify the real-world diagnostic accuracy of EyeArt for detecting rDR and to explore sources of heterogeneity (setting, camera type, vendor involvement, image gradability).

Rationale Diabetic retinopathy (DR) blinds more than one million people worldwide. Although annual dilated fundus examinations prevent vision loss, <50 % of patients attend screening, largely because ophthalmology capacity is limited. Autonomous artificial-intelligence systems such as EyeArt offer same-visit, point-of-care detection without human oversight and were cleared by the US FDA in 2020. EyeArt is now in clinical use, yet published accuracy estimates vary and no prior systematic review has focused solely on this platform. A rigorous synthesis of real-world performance is therefore critical for clinicians deciding whether to adopt EyeArt, for policymakers determining reimbursement, and for patients who may benefit from expanded access toscreening.

Condition being studied Diabetic retinopathy (DR)—microvascular retinal damage caused by chronic hyperglycaemia—is the leading cause of preventable blindness in working-age adults. "Referable DR" (rDR) denotes moderate non-proliferative DR or worse, or clinically significant diabetic macular oedema, requiring prompt specialist referral.

METHODS

Search strategy Databases: PubMed/MEDLINE, Embase, ClinicalTrials.gov from inception to 3 Apr 2025. Search string (PubMed example): ("diabetic retinopathy" OR "referable diabetic retinopathy" OR "vision-threatening diabetic retinopathy" OR "diabetic macular edema") AND ("EyeArt" OR "Eyenuk" OR "autonomous artificial intelligence" OR "deep learning" OR "machine learning") AND ("diagnostic accuracy" OR sensitivity OR specificity). No language or date limits. Reference lists of eligible papers and relevant reviews will be hand-searched; conference abstracts, medRxiv/arXiv preprints, and manufacturer white papers will be screened for unpublished data. Full search strategies for all sources are provided in Supplementary Table S3.

Participant or population Adults (≥18 years) with known or suspected diabetes (type 1 or 2) who underwent screening with EyeArt using color fundus photography in primary, secondary, or tertiary care, regardless of sex, ethnicity, or geographic region.

Intervention EyeArt software (any version), an FDA-authorised autonomous AI system that analyses 1- to 3-field, non-mydriatic or mydriatic color fundus images and automatically classifies patients as having rDR or not.

Comparator Reference standards include: (1) dilated slit-lamp biomicroscopy by a retinal specialist; (2) 2- or 4-wide-field stereoscopic fundus photography graded by certified reading-centre graders; (3) optical coherence tomography if incorporated into the reference protocol.

Study designs to be included Prospective cross-sectional studies, retrospective cohorts, or diagnostic test-accuracy studies reporting 2×2 data for EyeArt vs. a valid reference standard.

Eligibility criteria Inclusion: adult populations; EyeArt as the sole index test; color fundus photography; ability to construct 2×2 tables; peer-reviewed articles, full conference papers, preprints. Exclusion: paediatric cohorts; non-AI algorithms; imaging modalities other than fundus photo; duplicate datasets (largest/most recent kept); reviews, letters, editorials; insufficient data for accuracy estimation.

Information sources Electronic databases (PubMed, Embase, ClinicalTrials.gov).

Main outcome(s) Primary outcomes: pooled sensitivity and specificity of EyeArt for rDR, with 95 % CIs. Secondary diagnostic metrics: positive and negative likelihood ratios, diagnostic odds ratio, area under the SROC curve, and post-test probability using Fagan nomogram.

Quality assessment / Risk of bias analysis Two reviewers will use QUADAS-2 to assess risk of bias (patient selection, index test, reference standard, flow/timing) and applicability. Disagreements adjudicated by a third reviewer; results visualised with traffic-light plots.

Strategy of data synthesis A bivariate random-effects logistic regression will pool sensitivity and specificity. Between-study correlation will be modelled; SROC curve generated. Heterogeneity assessed via I^2 and χ^2. Meta-regression will explore predefined moderators. Publication bias evaluated with Deeks funnel asymmetry test. Analyses conducted in Stata 18 (metadta, midas).

Subgroup analysis Planned subgroups: study design (prospective vs retrospective); healthcare setting (primary vs tertiary); World-Bank income level; camera type (desktop vs smartphone); vendor involvement (yes/no); image gradability (>95 % vs ≤95 %).

Sensitivity analysis Re-analyse after excluding studies with high risk of bias, non-peer-reviewed sources, or outliers identified by influence diagnostics; compare fixed- vs random-effects; assess robustness to continuity-correction choices.

Language restriction None.

Country(ies) involved Taiwan.

Keywords EyeArt; diabetic retinopathy; artificial intelligence; fundus photography; autonomous screening; diagnostic accuracy; systematic review; meta-analysis.

Contributions of each author

Author 1 - Ting Wei Wang.
Email: twang180@jh.edu
Author 2 - Wei-Ting Luo.
Email: luomaggie1@gmail.com
Author 3 - Yu-Kang Tu.
Email: yukangtu@ntu.edu.tw
Author 4 - Yu-Bai Chou.
Email: ybchou@vghtpe.com.tw
Author 5 - Yu-Te Wu.
Email: ytwu@nycu.edu.tw