

Artificial Intelligence for Automated Detection of Diabetic Retinopathy in Primary Care

Day: Thursday

Time: 8:38 AM - 8:47 AM

Location: Ballroom

ID: 59

Submission Title:

Artificial Intelligence for Automated Detection of Diabetic Retinopathy in Primary Care

Purpose:

An automated, point of care, test could facilitate the identification of people with diabetic retinopathy (DR).

Methods:

A prospective, multi-center, intent-to-screen design study was conducted in a primary care setting, in people with diabetes. The study assessed diagnostic performance of an Artificial Intelligence (AI) system, incorporating deep learning based lesion detectors, for identification of DR including Diabetic Macular Edema (DME). The AI system was evaluated relative to standardized imaging and grading protocols by the Wisconsin Fundus Photograph Reading Center (FPRC). FPRC grading included Early Treatment Diabetic Retinopathy Study Severity Scale (ETDRS) and DME determinations from widefield stereoscopic photographs and macular Optical Coherence Tomography (OCT). More than mild DR (mtmDR) was defined as ETDRS level 35 or higher, and/or DME, in at least one eye. AI system operators underwent a standardized training protocol before study start; FPRC imaging was conducted by FPRC certified photographers.

Results:

A total of 900 participants were prospectively enrolled; a subset of 819 participants could be fully evaluated by both AI and FPRC. 198 (23.8%) had mtmDR; the AI system detected mtmDR at a sensitivity of 87.2% (95% CI, 81.8-91.2%) and specificity of 90.7% (95% CI, 88.3-92.7%). Imageability, the percentage of participants with completed FPRC grading and a disease level AI output, was 95.6% (95.0% CI, 94.0-96.8%).

Conclusions:

The AI system met predetermined sensitivity and specificity endpoints for the autonomous detection of more than mild DR, inclusive of DME, in people with diabetes in primary care settings. (Sponsored by IDx; [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02963441) NCT02963441)

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