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Automated diabetic retinopathy screening: large-scale study on consecutive patient visits in a primary care setting

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Background and Aims: Diabetic retinopathy (DR) is the leading cause of new-onset blindness among working-age adults in the western world. Vision loss due to DR is preventable by early diagnosis and intervention, and with the large and growing diabetic population, fully-automated DR screening is becoming essential. EyeArt is a computerized cloud-based DR screening system that automatically analyzes multiple color fundus images captured during a patient visit/encounter and provides a "refer" or "no refer" screening recommendation for patients. A "refer" recommendation is provided when the images indicate (i) moderate non-proliferative DR (NPDR) or higher on the International Clinical Diabetic Retinopathy (ICDR) severity scale and/or (ii) presence of surrogate markers for clinically significant macular edema (CSME) defined to be hard exudates within one disc of the macula.

This study evaluates the safety and efficacy of EyeArt version 2.0 for automated DR screening on a large set of 78,685 consecutive patient visit/encounters obtained from the EyePACS DR telescreening program covering over 300 primary care clinics across the United States. We report the screening sensitivity, specificity, and area under the receiver operating characteristic curve (AUROC) measures.

Materials and Methods: 78,685 consecutive patient encounters (totaling 627,490 images captured between January 2014 and May 2015) were obtained from the EyePACS database without any patient identification data, each with 1-38 images including external eye images. The DR severity on the ICDR scale and indication of surrogate markers for CSME provided by EyePACS graders was the clinical reference standard. Prevalence of encounters with moderate NPDR or higher or with surrogate markers for CSME was 20.1% and prevalence of encounters with potentially treatable DR (severe NPDR or proliferative DR) was 5.3%.

EyeArt analyzed these images and produced a "refer" or "no refer" screening recommendation for each patient. Encounters with fewer than two gradable retinal images were automatically flagged as non-screenable, given a "refer" recommendation, and included in the performance analysis.

Results: EyeArt's screening sensitivity was 91.7% (95%CI: 91.3%-92.1%) and specificity was 91.5% (95%CI: 91.2%-91.7%). This corresponds to 19,728 "refer" recommendations (including 545 encounters flagged by EyeArt as non-screenable) and 1309 false negatives out of which 95.3% had moderate NPDR and did not meet the general treatment criteria. The AUROC was 0.968 (95%CI: 0.967-0.970). The sensitivity for referring potentially treatable DR was 98.5% i.e. less than 0.08% of the 78,685 cases had potentially treatable DR not detected by EyeArt.

Conclusions: EyeArt v2.0 achieves high sensitivity for detecting both referable DR and for potentially treatable DR at a high specificity making it both safe and effective for automated DR screening.