An observational study to assess if automated diabetic retinopathy image assessment software can replace one or more steps of manual imaging grading and to determine their cost-effectiveness

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A nnual diabetic retinopathy screening using digital photographs of the retina assessed by human graders is recognised as the best way to detect vision-threatening disease and reduce visual loss in patients with diabetes mellitus. Vision-threatening disease is referred to hospital eye services for review and possible treatment. With more than 3 million people in England diagnosed with diabetes mellitus, there has been increasing interest in automated systems that detect diabetic retinopathy on digital pictures (so-called automated retinal image analysis systems (ARIASs)) as a way of reducing the need for human graders and the cost of screening. This study compared commercially available ARIASs [IDx-DR (IDx, LLC, Iowa City, IA, USA), iGradingM (version 1.1; originally Medalytix Group Ltd, Manchester, UK, but purchased by Digital Healthcare, Cambridge, UK, at the initiation of the study, purchased in turn by EMIS UK, Leeds, UK, after conclusion of the study), Retmarker (version 0.8.2, Retmarker Ltd, Coimbra, Portugal) and EyeArt (Eyenuk Inc., Woodland Hills, CA, USA)] with human manual grading on retinal photographs from 20,258 consecutive patients seen in a NHS diabetic eye screening programme. IDx, LLC withdrew from the study, citing commercial reasons. The ability of the remaining three ARIASs to correctly identify patients with diabetic retinopathy was compared against trained human graders. Health-economic analyses were carried out to investigate whether or not it would save money if ARIASs replaced trained human graders in different parts of the screening pathway.

Two ARIASs, Retmarker and EyeArt, achieved an acceptable level of diabetic retinopathy detection in comparison with trained human graders. Retmarker and EyeArt had a modest rate of false alarms, where these ARIASs would identify that there was disease when no disease was actually present. The good detection rate and acceptable false-alarm rate make both ARIASs potentially cost-effective alternatives to human grading in NHS diabetic eye screening programmes.
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