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Diabetic retinopathy screening in general practice

A pilot study

Background
Early detection and treatment of diabetic retinopathy (DR) can prevent nearly all associated severe vision loss. We investigated the feasibility of DR screening using nonmydriatic cameras in two Australian primary care clinics.

Methods
Two general practitioners from Queensland photographed the retinas of patients with type 2 diabetes seen in their clinics during the 9 month study period. The patients were then photographed and assessed by two independent ophthalmologists. The ophthalmologists' assessments provided the reference standard. General practitioners' accuracy in determining photograph interpretability and DR diagnostic sensitivity and specificity were measured. The attitudes of GPs about the DR screening were also assessed.

Results
One hundred and fourteen patient participants provided 219 photographs. Two ophthalmologists read 158 photographs and deemed 61% (97/158) interpretable, but GPs tended to accept more photographs for interpretation. General practitioners' diagnostic sensitivity and specificity was 87% and 95% respectively. Participating GPs were very positive about expanding their clinical role into DR screening.

Discussion
General practice based DR screening was feasible and acceptable in the clinics studied, but photograph quality was an issue.

Type 2 diabetes mellitus (T2DM) is a serious chronic disease worldwide, resulting in significant personal, social and economic costs.[1] Approximately 850 000 Australians have T2DM, and based on results from four major Australian epidemiological studies, it is estimated that 25–35% of these have diabetic retinopathy (DR).[2] Diabetic retinopathy is the leading cause of preventable blindness in adults.[3] Early detection and appropriate treatment can prevent nearly all severe vision loss and blindness from DR.[4]

The early stages of DR are clinically silent, and therefore systematic screening is indicated. The National Health and Medical Research Council (NHMRC) recommends biennial DR screening for people with diabetes and no evidence of DR, and annual assessment for Indigenous Australians and those with DR.[2] However, only about 50% of patients achieve this, and even the presence of DR is not a predictor of access to appropriate screening and monitoring.[5,6]

So why don't patients with diabetes access appropriate DR screening? In Australia, most publicly funded DR screening is provided by ophthalmologists and optometrists. However, there are long waiting lists for ophthalmology outpatient services, and access can be particularly difficult for patients from culturally and linguistically diverse backgrounds, or who live distant to these services.[7] Diabetes Australia's *Guidelines for type 2 diabetes* recommend that general practitioners regularly screen and monitor patients for most diabetic complications, but not necessarily DR,[8] the provision of general practice based DR screening in the context of regular diabetes reviews, a 'one-stop-shop' has potential to increase screening rates.[9–11] We conducted a pilot project to determine the feasibility of DR screening by GPs using nonmydriatic cameras.

Methods

Two GPs in two separate clinics in the suburb of Inala, in outer metropolitan Brisbane (Queensland), participated in the pilot study.

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One clinic, an indigenous health service, opportunistically recruited patients attending for their Diabetes Annual Cycle of Care visits. The other, a general practice based, multidisciplinary, integrated primary/specialist level clinic for patients with T2DM,[12] recruited patients at their first diabetic clinic visit. All patients with T2DM, 18 years of age or more attending either clinic between 16 September 2007 and 31 May 2008, were invited to participate in this study and informed consent was obtained before any photographs being taken.

The two participating GPs had links with The University of Queensland Discipline of General Practice (UQDGP) and were keen to develop advanced skills in primary eye care. They completed an online upskilling program offered by the UQDGP and accreditation assessment with the Royal Australian and New Zealand College of Ophthalmologists Queensland Faculty. Accreditation assessment involved achievement of ≥75% concordance (compared with two ophthalmologists) in interpreting 30 training retinal photographs, under examination conditions. Interpretation included diagnosis and grading of DR, detection of diabetic maculopathy, and development of appropriate referral plans. Training and assessment took approximately 6 hours.

Participants had single photographs taken of each retina using Canon nonmydriatic CR-1 digital retinal cameras by practice nurses trained in their use. Six patients required pupil dilation, all from the indigenous health clinic. The GPs read and interpreted the photographs of their clinic's patients, using a reporting sheet developed for this project by the ophthalmologists. Photographs were then independently read by two of the three project ophthalmologists who were masked to the GPs' assessment. Patients requiring ophthalmic assessment were referred to the local tertiary hospital ophthalmology outpatient clinic.

We used semistructured telephone interviews to explore the GPs' experiences and attitudes to DR screening in general practice.[13] Interviews took approximately 15 minutes. Notes were taken during the interviews with key quotes recorded verbatim and detailed summaries written immediately afterward. The first author coded the summaries, and identified and classified recurrent themes.[14] Participating GPs reviewed the themes to ensure accuracy and completeness.

Statistical analysis

Our key outcome measures were:

- the GPs' accuracy in determining the interpretability of the photographs, and
- the GPs' DR diagnostic sensitivity and specificity.

Diagnostic concordance was determined only when the photograph had been deemed interpretable by the GP and two ophthalmologists.

Agreement between ophthalmologists, and between GPs and ophthalmologists, was measured using concordance and Kappa statistics with associated 95% confidence intervals. McNemar's test compared the symmetry of the discordant observations. Where appropriate, the GPs' accuracy in determining the interpretability of the photographs, and diagnosing DR and maculopathy was assessed using sensitivity, specificity, positive predictive value, and negative predictive value estimates, using the ophthalmologists' assessments as the reference standard. All statistical calculations were undertaken using Stata version 10 and α=5% defined statistical significance.

The Princess Alexandra Hospital Human Research Ethics Committee approved the study.

Results

Sample characteristics

All eligible patients attending these clinics were invited to participate, and all patients (114) accepted. Photographs of both retinas were available for 105 patients, and single retinal photographs were available from the remaining nine patients. Of these 219 photographs, 158 photographs were assessed by two ophthalmologists and 144 were assessed by a GP and two ophthalmologists. As the focus of this pilot project is on determining the feasibility of DR screening in primary care, we did not collect data on the sociodemographic and clinical characteristics of patients.

Interpretability of the retinal photographs

Collectively, the ophthalmologists deemed 61% (97/158) of the retinal photographs interpretable. Concordance was generally high between ophthalmologists 'A' and 'B' (83%) and 'A' and 'C' (76%), (κ=0.59 and 0.50, respectively), and there were no systematic differences in their assessments (*Table 1*). General practitioner 'A' read 73 photographs and GP 'B' read 126. They deemed 74% (54) and 83% (105) interpretable, respectively, and were more likely than the ophthalmologists to deem photographs interpretable (McNemar's p<0.001). General practitioners' sensitivity and specificity in determining interpretability of the photographs cannot be assessed because of this discordance. Patients with photographs that were deemed uninterpretable were recalled for repeat photography or referred to the local ophthalmology outpatients department. Repeat photographs were not included in the analysis.

Diagnosis of diabetic retinopathy

Of the 97 photographs deemed interpretable by the ophthalmologists, 90 were assessed for the presence of DR. Diabetic retinopathy

was diagnosed in 12% (11/90) of these photographs (*Table 1*). Concordance was high between ophthalmologists 'A' and 'B' (91%) and 'A' and 'C' (88%), but combining assessments from ophthalmologists 'B' and 'C' revealed they were more likely than ophthalmologist 'A' to diagnose DR (p=0.04). Agreement between ophthalmologists 'A' and 'B' was substantial, κ=0.70, but was unable to be estimated between ophthalmologists 'A' and ''C due to the small numbers and the fact that there were no photographs in which both diagnosed DR.

The GPs' collective DR diagnostic sensitivity and specificity was 87% and 95% respectively, using ophthalmologist 'A' as the reference standard (he assessed every photograph whereas ophthalmologists 'B' and 'C' assessed subsets, and no systematic differences between ophthalmologists' DR diagnoses were identified) (*Table 2*). There were no systematic differences in the GPs' DR diagnostic abilities (Fisher's exact p=0.71); their combined diagnostic accuracy figures are reported in *Table 2*.

The GPs graded the retinopathy as the same or more severe than the ophthalmologist in all but seven instances – they missed a diagnosis of mild retinopathy in six instances, and graded moderate DR as mild in the remaining case.

Diagnosis of maculopathy

Of the 97 photographs deemed interpretable by the ophthalmologists, 87 were assessed for the presence of maculopathy. Maculopathy was diagnosed by the opthalmologists in 3% (3/87) of these photographs (*Table 1*). Concordance was high between ophthalmologists 'A' and 'B' (91%) and 'A' and 'C' (88%), and there were no systematic differences in their diagnoses (*Table 1*). The specificity of the GPs' diagnosis was high, but the low prevalence limits the value of the sensitivity calculations (*Table 2*).

Themes from the qualitative data

The two GPs were overwhelmingly positive about their involvement in this project, and the potential of general practice based DR screening to improve access and quality of care for people with diabetes. Key issues identified from the interviews are presented in *Table 3*.

Discussion

Our project has identified that general practice based DR screening has potential. The participating GPs' diagnostic sensitivity and specificity met the NHMRC DR screening criteria.[2] They were cautious in their grading of DR with a tendency to grade its severity the same or higher than the ophthalmologists. They were very positive about the experience, appreciating the opportunity to expand their

Table 1. Concordance and agreement between two ophthalmologists in assessing retinal photograph interpretability and diagnoses of diabetic retinopathy and maculopathy

	Total	Frequency of concordance between ophthalmologists						
		Positive assessment		Negative assessment				
	N	n	(%)	n	(%)	κ*	(95% CI)	*p* value†
Interpretability of photographs	158	97	(61)	33	(21)	0.58	(0.44, 0.72)	0.85
Diagnosis of retinopathy	90	11	(12)	70	(78)	0.65	(0.45, 0.86)	0.04
Diagnosis of maculopathy	87	3	(3)	81	(93)	0.65	(0.29, 1.00)	0.25

* Kappa statistic and associated 95% CI: κ>0.8 represents almost perfect agreement beyond chance, 0.60<κ≤0.80 represents substantial agreement, 0.40<κ≤0.60 represents moderate agreement, 0.20<κ≤0.40 represents fair agreement, 0.00≤κ≤0.20 represents slight agreement, and κ<0.00 represents no agreement beyond chance.[17]

† p value derived from an exact McNemar's test of symmetry

Table 2. Concordance, sensitivity, specificity, PPV, NPV and agreement between the GPs and ophthalmologist 'A' in assessing retinal photograph interpretability and diagnoses of diabetic retinopathy and maculopathy, with ophthalmologist 'A' as the reference standard

	Total	Frequency of concordance between ophthalmologist 'A' and GPs				Sensitivity	Specificity	PPV	NPV			
		Positive assessment		Negative assessment								
	N	n	(%)	n	(%)	(%)	(%)	(%)	(%)	κ‡	(95% CI)	*p* value§
Diagnosis of retinopathy	90	13	(14)	71	(79)	87	95	76	97	0.77	(0.60, 0.95)	0.69
Diagnosis of maculopathy	87	1	(1)	81	(93)	20	99	50	95	0.26	(–0.18, 0.70)	0.38

‡ Kappa statistic and associated 95% CI: κ>0.8 represents almost perfect agreement beyond chance, 0.60<κ≤0.80 represents substantial agreement, 0.40<κ≤0.60 represents moderate agreement, 0.20<κ≤0.40 represents fair agreement, 0.00≤κ≤0.20 represents slight agreement, and κ<0.00 represents no agreement beyond chance[17]

§ p value derived from an exact McNemar's test of symmetry

PPV = positive predictive value

NPV = negative predictive value

clinical practice, and provide their patients with improved access to DR screening and more comprehensive care. However, our pilot project involved only two GPs with an interest in primary eye care practicing in non-mainstream general practices.

The success of such screening programs rests on photograph interpretability. A relatively high proportion of retinal photographs were deemed uninterpretable by the ophthalmologists. This could be due to high prevalence of comorbidities such as cataracts, or it could be due to poor photographic technique. To improve the photo quality, the practice nurses taking the photographs need support and nurturing while they are gaining experience and confidence, and real time feedback about the quality of the photographs. Pupil dilation should be mandatory in patients over 60 years or when two sets of photographs have been rejected because of poor quality. General practitioner vigilance in rejecting photographs also needs to increase, and is likely to with more experience and confidence, highlighting the value of ongoing training and support from the ophthalmologists during the training phase.

There was a considerable discrepancy between the number of patients involved, and the final number of photographs included in the analysis. This pilot has identified the importance of good record keeping within the practice, and good administrative support to ensure timely follow up if images or reports are not available to be forwarded to the ophthalmologists.

Having two ophthalmologists assess each retinal photograph was a strength of our study, although it also introduced a level of administrative complexity. Because interpretation of the photographs requires an informed judgment by the assessor, inter-rater error is always possible and demonstrated by lack of 100% concordance between the ophthalmologists in our study. However, we identified no systematic differences between ophthalmologists and were therefore able to use the one ophthalmologist who has read all photographs as the reference standard against which the GP's assessments were compared. For reliability studies such as this, the use of two experts and a systematic approach to assessing and resolving discordance should assist in ensuring the integrity of the reference standard.

The increasing prevalence of T2DM is necessitating changes in the delivery of care. Primary care based DR screening could increase patient access to timely screening by incorporating it into Diabetes Annual Cycle of Care visits.[15,16] Additionally, reducing the number of screening referrals to ophthalmologists of people without DR could improve access for patients with severe retinopathy who require specialist eye services. We have demonstrated that the participating GPs' rapidly acquired the appropriate screening skills and applied them in their existing primary care setting. Further work is needed to ensure the generalisability of these results by expanding the scope of the project to include more GPs and mainstream general practices, exploring the cost effectiveness of this approach, and assessing the acceptability of this model to patients.

Table 3. Themes emerging from the GP interviews

General practitioners described feeling:

- 'Incredibly empowered and upskilled', which led to increased confidence in diabetes care and other areas of clinical practice
- More involved in the care of their patients because they could use evidence of retinal disease for educating and motivating patients to focus on improving blood sugar control and attend specialist appointments
- Surprised at how many patients had abnormal retinas and glaucoma
- Improved collegiality with specialists because of increased knowledge and confidence
- Happy they could save their patients without retinopathy from having to attend ophthalmology outpatients or a private ophthalmologist for screening
- That the provision of a general practice based 'one-stop-shop' for all diabetes screening increased the proportion of patients being screened for diabetic retinopathy and increased the appropriateness of referrals benefitting patients and hospital staff
- That GP training needed to include assessment of interpretability of photographs
- That the data obtained through this project was a great opportunity for research, particularly by linking retinopathy, blood sugar control and other complications of diabetes
- That it took time and support for the practice nurses to be trained and gain sufficient confidence to feel competent taking the photographs
- Some patients did not appreciate the screening as it increased the length of the time they were at the practice, and particularly while the nurses were being trained some 'got a bit edgy about the time taken and the fuss about getting the photo right'

General practitioners perceived the following barriers to more widespread implementation of diabetic screening in general practice:

- the necessity of having a darkened room for the camera
- the cost of the camera
- time required for training of GPs and practice staff
- time involved in taking and reading the photos
- the absence of a Medicare rebate for DR screening

Implications for general practice

- Diabetic retinopathy is the leading cause of preventable blindness in adults – early detection and appropriate treatment can prevent nearly 100% of severe vision loss and blindness.
- Only about 50% of people with diabetes access appropriate screening.
- General practice based DR screening, integrated into the Diabetes Annual Cycle of Care, has the potential to improve access to regular DR screening and enable GPs to provide more comprehensive care to their patients with diabetes.

Conflict of interest: none declared.

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