A 'fail-safe' screening programme for diabetic retinopathy

ABSTRACT

Objective: To improve screening for diabetic retinopathy in a hospital diabetic clinic through the use of the audit process.

Design: Comparison of an existing system of screening for diabetic retinopathy (a specialist optometrist using ophthalmoscopy alone) with a new system in which a specialist optometrist examined retinal Polaroid photographs taken through pharmacologically dilated pupils and combined this with ophthalmoscopy in all cases except when the photographs were perfect and definitely showed no retinopathy. In this new system, the optometrist could discuss cases of uncertainty with a diabetes physician while the patient was still in the clinic with eyes dilated.

Setting: Inner city hospital diabetes clinic.

Subjects: 289 hospital diabetic clinic patients not already attending an ophthalmologist; a consecutive series of 144 such patients for the first audit, 145 for the repeat audit.

Main outcome measures: Assessment of each screening system against a gold standard. For the first audit this was agreement by two of four diabetes physicians, who combined examination of the photographs with the findings of dilated ophthalmoscopy, on the classification of the retinala of each patient, guided by standard European criteria. For the second audit, the gold standard was enhanced by discussing the photographs and findings of all patients with an independent ophthalmologist. For patients requiring referral, a second ophthalmologist also commented on the case.

Results: The addition of retinal photography to universal pupil dilatation, and the availability of diabetes physician back-up to discuss cases of uncertainty, greatly increased the optometrists' detection rate. Sensitivities for the first (ophthalmoscopy only) and second (ophthalmoscopy plus photography plus diabetologist back-up) audits were, respectively, 71.4% vs 100% for sight-threatening retinopathy, 33% vs 100% for retinopathy requiring six-month review, and 40.3% vs 97.2% for any retinopathy (p=0.002).

Conclusions: Optometrists specialising in diabetic retinopathy using Polaroid retinal photography and ophthalmoscopy, both through dilated pupils, backed up by experienced diabetologists to discuss cases of uncertainty, could form the basis of a retinopathy screening service that accurately identifies and categorises retinopathy and does not miss sight-threatening cases.

Studies using direct ophthalmoscopy through dilated pupils to screen for diabetic retinopathy have recorded the following miss rates for sight-threatening diabetic retinopathy:

- general practitioners: 45%1 and 48%2
- high-street optometrists: 52%1
- hospital physicians, 27%3 and 33%1
- ophthalmologists 35%4 and 36%5.

This suggests that direct ophthalmoscopy on its own is unreliable as a means of screening for sight-threatening retinopathy, no matter who undertakes it. Studies using 45° field retinal photography through undilated pupils have not been noticeably different. The large Department of Health and Social Security sponsored, multicentre study of 3,318 patients concluded that:

...in a setting close to routine screening, the sensitivities of all screening methods are poor... , the routine use of any of these single screening methods will fail to detect a large proportion of cases of sight-threatening diabetic retinopathy.

The Newcastle study of 2,159 patients demonstrated that retinal photography through undilated pupils and ophthalmoscopy through dilated pupils both missed significant amounts of serious retinopathy detected by the other. In view of this, and as mydriasis greatly improves retinal photographic quality, it has been argued that screening for diabetic retinopathy should ideally combine retinal photography and ophthalmoscopy. We therefore reviewed our existing ophthalmoscopy-based diabetic retinopathy screening system. In the light both of the result of this review and the reports of other studies, our system was changed to involve dual modality screening. It was then reassessed with regard to its efficacy.

The initial review

Patients and methods

At the time of the initial review the system of diabetic retinopathy screening adopted in the hospital diabetic clinic was direct ophthalmoscopy by a specialist optometrist. The optometrist concerned had considerable experience and expertise with diabetic retinopathy screening and had been involved in the screening of large numbers of hospital diabetic patients over several years. The system used was to
measure visual acuity and then to perform ophthalmoscopy through undilated pupils. If a clear view of the retina was obtained, the findings were recorded and screening was considered to have been completed; if there was any difficulty obtaining a clear view of the retina, tropicamide mydriatic drops were instilled and ophthalmoscopy repeated after mydriasis. Before making any change, it was felt appropriate to assess the existing method.

A consecutive series of 144 hospital diabetic clinic patients undergoing retinopathy screening as part of their routine annual diabetic review (mean age, 58 years; range, 17–90 years; 78 women), but not already attending an ophthalmologist, were re-examined after routine eye-screening had been completed by the optometrist. For the re-examination, pupils were dilated with tropicamide mydriatic drops in all cases, and 45° field Polaroid retinal photographs were obtained with a Canon CR4 45NM retinal camera. In each case, two of four diabetes physicians (REJR, CFC, AJK, KGT), combining examination of the Polaroids with the findings from dilated direct ophthalmoscopy, agreed the classification of the retinas of each patient. Patients were classified as having:

- no retinopathy
- retinopathy requiring 12-month review
- retinopathy requiring six-month review
- retinopathy requiring referral to an ophthalmologist.

The categorisation was guided by the standard European working party criteria. As further back up, an ophthalmologist with a special interest in diabetic retinopathy (ophthalmologist A (EEK)) commented on each case which required referral. Thus, the gold standard in this assessment was examination of mydriatic photographs plus ophthalmoscopy by two diabetes physicians and agreement by them on categorisation, plus all patients referred being assessed by an ophthalmologist.

**Results**

The optometrist felt the need to dilate pharmacologically 76/288 (26.4%) of the eyes screened. According to the assessment of the diabetologists combining retinal photography and ophthalmoscopy, diabetic retinopathy was present in 62/288 (21.5%) eyes. Using ophthalmoscopy alone, this retinopathy was detected by the optometrist in only 25 (40.3%) of these 62 eyes. Most of the 37 (59.7%) missed cases were minimal background diabetic retinopathy. The diabetologists combining retinal photography and ophthalmoscopy classified 7/144 (3.8%) patients as having retinopathy requiring referral to an ophthalmologist according to standard European criteria. The optometrist using ophthalmoscopy alone detected 5 (71.4%) of these 7 cases. Ophthalmologist A agreed that referral was appropriate in all seven cases referred, according to European criteria. The two cases missed by the optometrist were:

- a large circinate formation of hard exudates lateral – but next – to the macula in a patient in whom the optometrist had felt that a good view had been obtained without pharmacological dilatation of the pupil
- a small cluster of hard exudates at the macula in a patient whose eyes were pharmacologically dilated but who also had partial cataract, making ophthalmoscopy difficult.

The diabetologists combining retinal photography and ophthalmoscopy classified 3/144 (2.1%) patients as having retinopathy not yet bad enough to require referral to an ophthalmologist but bad enough to require six-month review. The optometrist using ophthalmoscopy alone classified 1 (33%) of these 3 cases as requiring six-month review but, whilst detecting the presence of the retinopathy in the other two, noticed only occasional microaneurysms, failing to spot in both cases small circinate formations of hard exudates lateral to the macula.

**Change of practice and repeat audit – closure of audit loop**

In view of the experience in the initial review and the many reports of the unreliability of direct ophthalmoscopy, even if all pupils are dilated and the ophthalmoscopy is highly experienced (ie diabetologist or ophthalmologist), the screening system in the hospital clinic was changed. A specialist optometrist was still considered an optimum screener, but the screening system became as follows: visual acuity was assessed, pupils pharmacologically dilated in all cases and then retinal Polaroids taken. The optometrist examined the Polaroids in a good light and, if they were of high quality, without any evidence of diabetic retinopathy, and no unexplained abnormality of visual acuity, the patient was classified as 'no diabetic retinopathy' and no further examination was undertaken. If the Polaroids were less than perfect, if there was any possibility of retinopathy or an unexplained abnormality of visual acuity, careful direct ophthalmoscopy was also undertaken, guided by the Polaroids, in particular aiming to examine those parts of the retina beyond the reach of the Polaroid. Any lesions on the Polaroids about which there was uncertainty were carefully sought and examined with the ophthalmoscope. Senior diabetes physicians undertaking a large diabetic clinic were on hand to discuss any cases of uncertainty while the patient was still present with eyes dilated. Once this new eye-screening service was established, an assessment similar to the initial one was undertaken.

**Patients and methods**

The assessment was conducted, like the initial one, on a consecutive series of 145 hospital diabetic clinic patients undergoing retinopathy screening as part of their routine annual diabetic review (mean age, 61 years; range, 32–88 years; 63 female), and not already attending an ophthalmologist. The gold standard assessment was the same as
before, but further enhanced by discussing the photographs and findings of all patients with an independent ophthalmologist with a special interest in diabetic retinopathy (ophthalmologist B (JMG)). The optometrist classified patients into one of the same four categories as previously, with the addition of a fifth category of 'discuss with diabetes physician'. As with the initial assessment, ophthalmologist A, to whom patients requiring it were referred, also commented on each such case. Again the standard European criteria for referral were used.

Results

Table 1 shows the results of the first and second assessments. Ophthalmologist A agreed that referral was appropriate, according to European criteria, in all 10 cases referred. The addition of retinal photography and universal pupil dilatation to ophthalmoscopy with selective pupil dilatation greatly increased the optometrist's detection rate.

When using ophthalmoscopy plus photography, the optometrist categorised only 14/145 (10%) patients as 'discuss with diabetologist'. Of these 7/14 were referred to an ophthalmologist, 6/14 were given a six-month review, and only 1/14 a 12-month review.

Discussion

The rate of failure to detect any diabetic retinopathy by the optometrist using ophthalmoscopy alone (59.7%) was similar to that by diabetic clinic doctors (undilated pupils, 76%; dilated pupils, 56%19). The addition of retinal photography within the new framework reduced this high rate of failing to detect any retinopathy by ophthalmoscopy to 2.8% and no cases of sight-threatening retinopathy were missed. The optometrist did not achieve this result by categorising too many cases as 'discuss with diabetologist'. The 10% of cases for discussion were almost entirely cases of serious retinopathy on the borderline between requiring immediate referral to an ophthalmologist and requiring six-month review. It might be argued that ophthalmoscopy alone with pupil dilatation in all cases by the optometrist might have achieved a similar result. As discussed above, this seems unlikely in view of the many studies showing the inadequacy of dilated ophthalmoscopy alone, even when undertaken by an experienced diabetologist or ophthalmologist. When the first assessment showed that change in the screening system was required, we did not feel that a further assessment of dilated ophthalmoscopy on its own could be justified ethically before introducing and evaluating our system of combined modality screening.

A recent study demonstrated that combined modality screening in a primary care setting improved detection rates for sight-threatening diabetic retinopathy to 80–90%. The current study shows the further improvement that can be obtained in a hospital clinic setting by experienced (in diabetic retinopathy) optometrists, as opposed to standard high-street optometrists, undertaking the screening, together with immediately available back-up from a senior diabetes physician to discuss cases of uncertainty. The current study is the first to have achieved a 100% detection rate for sight-threatening diabetic retinopathy. In view of this, and the high sensitivity with regard to detection of all forms of diabetic retinopathy, we have termed our system 'fail-safe' diabetic retinopathy screening. We now aim to provide it for all diabetic patients attending the hospital diabetes clinic, and have also opened it up to patients whose diabetes is treated entirely in the community by providing 'diabetic retinopathy screening only' clinics. To conserve the resource of these special clinics, patients in whom the 'fail-safe' system has found no retinopathy are given an appointment for further 'fail-safe' screening in two years' time. The idea is that the general practitioner or high-street optometrist undertakes ophthalmoscopy in the

Table 1. Comparison of diabetic retinopathy present and detected by the two methods of screening.

| No. of patients (eyes) | Specialist optometrist using ophthalmoscopy alone | Specialist optometrist using ophthalmoscopy + photography and diabetologist back-up |
|-----------------------|--------------------------------------------------|-------------------------------------------------------------------------|
|                       | 144 (288)                                        | 145 (290)                                                               |
| All eyes with retinopathy | 62/288 (21.5)                                  | 72/290 (24.8)                                                          |
| Presence of any retinopathy detected | 25/62 (40.3)                                  | 70/72 (97.2*)                                                           |
| Eyes with retinopathy requiring 12-month review | 52/288 (18.1)                                 | 53/290 (18.3)                                                          |
| Patients with retinopathy requiring 6-month review | 3/144 (2.1)                                  | 9/145 (6.2)                                                             |
| Patients with retinopathy requiring referral | 7/144 (3.8)                                   | 10/145 (6.9)                                                            |
| Retinopathy requiring 6-month review detected | 1/3 (33)                                      | 9/9 (100)                                                               |
| Retinopathy requiring referral detected | 5/7 (71.4)                                    | 10/10 (100)                                                             |

* p=0.002 compared to ophthalmoscopy alone.
intervening year, to comply with the usual guideline that there should be some form of annual eye-screening.

Screening in the community offers a number of advantages. In many areas, systems for diabetic retinopathy screening are being established based on community optometrists in primary care. In the current study, the optometrist categorised 10% of patients as 'discuss with diabetologist'. These were cases on the borderline between requiring referral to an ophthalmologist for treatment and requiring six-month review. Our study would suggest that a sufficiently trained and experienced optometrist, using combined modality screening in a primary care setting, could identify with high sensitivity and specificity the group of patients requiring referral and those on the borderline. These could then be referred to a diabetologist/ophthalmologist for further assessment and follow-up according to local arrangements. Thus, though our results apply particularly to screening in a secondary care environment, they can probably also be usefully extrapolated to the primary care setting.

In 1992, a patient settled out of court and received £225,000 from a health authority, claiming that she had gone blind from diabetic retinopathy because she had not been adequately screened, detected and treated.\(^2\) We conclude that specialist (in diabetic retinopathy) optometrists using Polaroid retinal photography and ophthalmoscopy both through dilated pupils, backed up by experienced diabetologists to discuss cases of uncertainty, could form the basis of retinopathy screening that accurately identifies and categorises retinopathy, and does not miss such sight-threatening cases.

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Address for correspondence: Dr R E J Ryder, Diabetes Unit, City Hospital NHS Trust, Dudley Road, Birmingham B18 7QH.

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Gayle Sawyer, British Travel Health Association, 4 Bedford Square, London WC1B 3RA.