Effectiveness of optometrist screening for diabetic retinopathy using slit-lamp biomicroscopy

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Abstract

Purpose **To assess the effectiveness of optometrists as screeners for diabetic retinopathy using slit-lamp binocular indirect ophthalmoscopy through dilated pupils.**
Methods **Prospective study of a screening scheme. Screening was performed by 27 locally accredited optometrists in their practice. The referral protocol used a new simple grading system of retinopathy, especially designed for use in an optometrist screening programme. All positive referrals and 10% of negative referrals were re-examined by an ophthalmologist. Sensitivity, specificity, likelihood ratios and technical failure rates were calculated.**
Results **The optometrists screened 4904 people with diabetes in 18 months. 'Subthreshold' (screen negative) reports accounted for 4438 (90.5% of 4904); 429 (9.67%) of these were re-examined at secondary screening. There was disagreement regarding grading in 13 patients, of whom 5 (1.16% of 429) had sight-threatening retinopathy (STDR); this extrapolates to 52 patients if all the 4438 test-negatives had been examined. Of the 371 'threshold' patients, 112 (30.18%) were false positives; the commonest cause for false positive referral was drusen in patients with background diabetic retinopathy. The sensitivity for identification of STDR was 76% (95% CI 70% to 81%) and specificity 95% (95% CI 95% to 96%). The likelihood ratio of a positive test indicating STDR was 16.54 (95% CI 14.17 to 19.23) and that of a negative test 0.25 (95% CI 0.20 to 0.32). The technical failure rate was 0.2%.**
Conclusions **Suitably trained and accredited community optometrists performed well when screening for diabetic retinopathy using slit-lamp biomicroscopy through a dilated pupil. This was facilitated by the use of simple grading and referral criteria. The sensitivity, positive likelihood ratio and specificity were high.**

Key words Diabetes mellitus, Mass screening, Optometry, Retinopathy

Diabetic retinopathy satisfies all the cardinal criteria necessary to justify the establishment of a screening service as it has a known natural history, an asymptomatic phase when screening can identify at-risk patients, and effective treatment can be delivered and the target population can be readily identified. In spite of this, establishment and uptake of screening services have been patchy in the UK and elsewhere,[1–3] with great variation in screening methods and population coverage. Because of this approximately 300 cases of preventable visual loss occur amongst people with diabetes annually in the UK.[4] The UK national screening committee is considering the topic as a possible national priority.[5] The present debate centres on what is the most suitable test and who is the most suitable screener. The candidate methods of screening are retinal photography, direct ophthalmoscopy and slit-lamp biomicroscopy. A recent systematic review[6] and accompanying editorial[4] concluded that mydriatic retinal photography was effective, while there was little or no evidence to support direct ophthalmoscopy as a method of screening for diabetic retinopathy; adequate studies reporting the effectiveness of screening using slit-lamp biomicroscopy were not available in the literature.

The Wirral Diabetic Eye Study has examined the performance of locally accredited, community-based optometrists as screeners for diabetic retinopathy using slit-lamp biomicroscopy. In this report we present the results of the first 18 months of the screening scheme, with analysis of the results to establish the sensitivity, specificity and likelihood ratios of the screening test.

Methods

Case acquisition

Our district diabetes register collected demographic data of all known people with diabetes from 64 of 65 general practices in the area, all hospital sites running diabetes clinics and laboratory Hb_{A1c} reports. This process

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Table 1. *Grading system used by optometrists*

Subthreshold	N:	*Normal*
	ST:	*Background retinopathy (BDR)*
		BDR without features A, B, C or D
Threshold:	A:	*BDR with maculopathy*
		Exudate or retinal thickening within temporal arcades
	B:	*Moderate/severe BDR*
		Severe retinal haemorrhage (blot) in at least two quadrants, OR cotton wool spots, venous beading, IRMA present in any quadrant
	CV:	*Proliferative*
		NVD or NVE
	D:	*Advanced diabetic eye disease*
		Preretinal or vitreous haemorrhage
Comments:		Unexplained/uncorrectable poor visual acuity
		Other unrelated findings

This is accompanied by fundus photographs for guidance.
NVD, new vessels on disc; NVE, new vessels elsewhere.

identified 7652 people with diabetes representing 2.12% of the target population of 36 1050; the details of this process have been reported elsewhere.[7] All people with diabetes who were not already under the care of the hospital eye service were invited to have a free eye-screening test by an accredited optometrist at a convenient optometry practice.

Training and accreditation of optometrists

All optometrists in the area were invited to participate. Respondents attended an initial lecture, following which they attended hospital eye clinics with an ophthalmologist (S.P., L.G.C. or R.P.P.). Here, they received individual 'hands-on' training in fundus examination using a 90 and 78 D lens and gained experience in the examination and grading of fundi with diabetic retinopathy. Once the individual felt competent with these skills, they undertook an assessment. This consisted of correctly grading 12 consecutive patients with diabetic retinopathy according to the grading system used for primary screening (Table 1). Four optometrists failed to attend enough clinical sessions to complete the assessment and were therefore not accredited. Twenty-seven optometrists achieved the required standard and were accredited to screen for diabetic retinopathy.

Screening process

Screening was performed by the optometrists in their own practice. Examination consisted of a standard eye test including measurement of visual acuity and refraction, together with a dilated biomicroscopic fundus examination for assessment of diabetic retinopathy status. It was mandatory to dilate pupils and to use slit-lamp biomicroscopy for fundus examination. A new simple grading system was used by the optometrists (Table 1). It was thought to be essential that the grading system used was clear but concise, so that it could be learnt and reproduced easily. Because of this, established grading systems like those used in research studies[8–10] and in photographic screening systems[11,12] were considered to be unsuitable for use in our programme and a new system was devised. All patients who had a 'threshold' or ungradable result at screening and 10% of those who had a 'subthreshold' result were re-examined by an ophthalmologist (S.P.). At this examination, Snellen visual acuities were recorded and fundus examination was performed through dilated pupils using 90 D and 60 D lenses, supplemented by Goldmann contact lens examination and binocular indirect ophthalmoscopy as needed. A more detailed grading system was used at this examination (Tables 2, 3). Sight-threatening diabetic retinopathy (STDR) was defined as levels 30, 40 and 70 for retinopathy and/or levels 3 and 4 for maculopathy. For all false-positive referrals, we tried to ascertain the reason that may have led to this, on the basis of the reported findings, the drawing on the report and the findings at secondary screening. At re-examination, the examining ophthalmologist's practice was to determine the grading of retinopathy and enter this into the database before seeing the optometrist's report.

Table 2. *Levels of retinopathy in the Wirral Diabetes Eye Study used at re-examination by ophthalmologist*

Level	Severity	Definition
10	No retinopathy	No retinopathy
20	Background retinopathy (NPDR)	Mild background change, not satisfying criteria for 'moderate' or 'severe' retinopathy
30	Moderate NPDR	Any one of: ● Four quadrants of haemorrhage (blot) ● Two quadrants of venous beading ● IRMA
40	Severe NPDR	Any two of the three criteria for 'moderate' NPDR'
60	PDR stabilised	Inactive fibrous proliferations ± photocoagulation scars
70	PDR	Active proliferative retinopathy ± photocoagulation scars
90	Ungradable	Due to media opacity

Grading done according to biomicroscopic appearance.
Ensure area up to equator has been assessed.

Table 3. *Levels of maculopathy in the Wirral Diabetes Eye Study used at re-examination by ophthalmologist*

Level	Definition
0	No macular oedema
1	Questionable
2	Macular oedema but not clinically significant
3	Circinate ring but not clinically significant macular oedema
4	Clinically significant macular oedema
5	Macular oedema lasered previously, now stable
6	Non-diabetic maculopathy
90	Ungradable

Grading done according to biomicroscopic appearance.
Clinically significant macular oedema:
1. Thickening of retina < 500 μm from centre of macula.
2. Hard exudate with thickening of adjacent retina < 500 μm from centre of macula.
3. A zone of retinal thickening, > 1 disc area located < 1 disc diameter from centre of macula.

Disc assumed to be 1500 μm diameter; 500 μm = 1/3 disc diameter.

Data collection and analysis

Data from all the optometrist reports, and details of re-examination by the ophthalmologist, were entered into a custom-designed database. Statistical analysis was performed using StatsDirect version 1.6 software and the tools available at The Centre for Evidence Based Medicine website (Oxford, UK).

Results

Fig. 1 summarises the results obtained during the 18 month study period. Of the 4904 people with diabetes screened during this period, 52.8% were male and 47.2% were female. There were 32 people with diabetes aged under 16 years, 2268 in the 16–64 year age group and

Table 4. *Reasons for false positive referrals* (n = 112)

Reason for false positive referral	Number
Drusen/macular degeneration: without diabetic retinopathy = 16 with BDR only = 29	45
Maculopathy treated by photocoagulation in the past	4
Vein occlusion	6
High myope with BDR only	3
Macular oedema queried by screener	4
Poor view due to cataract	3
No reason found	47
Total	*112*

BDR, background diabetic retinopathy.

2604 aged over 64 years. We report test positives and negatives according to our grading system and also the number of patients with STDR in the appropriate groups. The reasons for false-positive referrals are summarised in Table 4.

As we had only examined a sample (9.6%) of the people with diabetes reported as test-negative by the screening test, we extrapolated these results to the total population of people with diabetes who screened negative. Thus 134 people with diabetes would have satisfied the criteria for a positive test although they tested negative and, more importantly, 52 people with diabetes would have had STDR even though they were test-negative.

The screening test that we used had a sensitivity of 66% (95% CI 65% to 67%) and a specificity of 97% (95% CI 97% to 98%), when applying the grading and referral criteria described in Table 1. The likelihood ratio of a positive test was 25.98 (95% CI 21.36 to 31.60) and that of a negative test was 0.35 (95% CI 0.30 to 0.40). For detection of STDR, the sensitivity of the test was 76% (95% CI 70% to 81%) and specificity 95% (95% CI 95% to
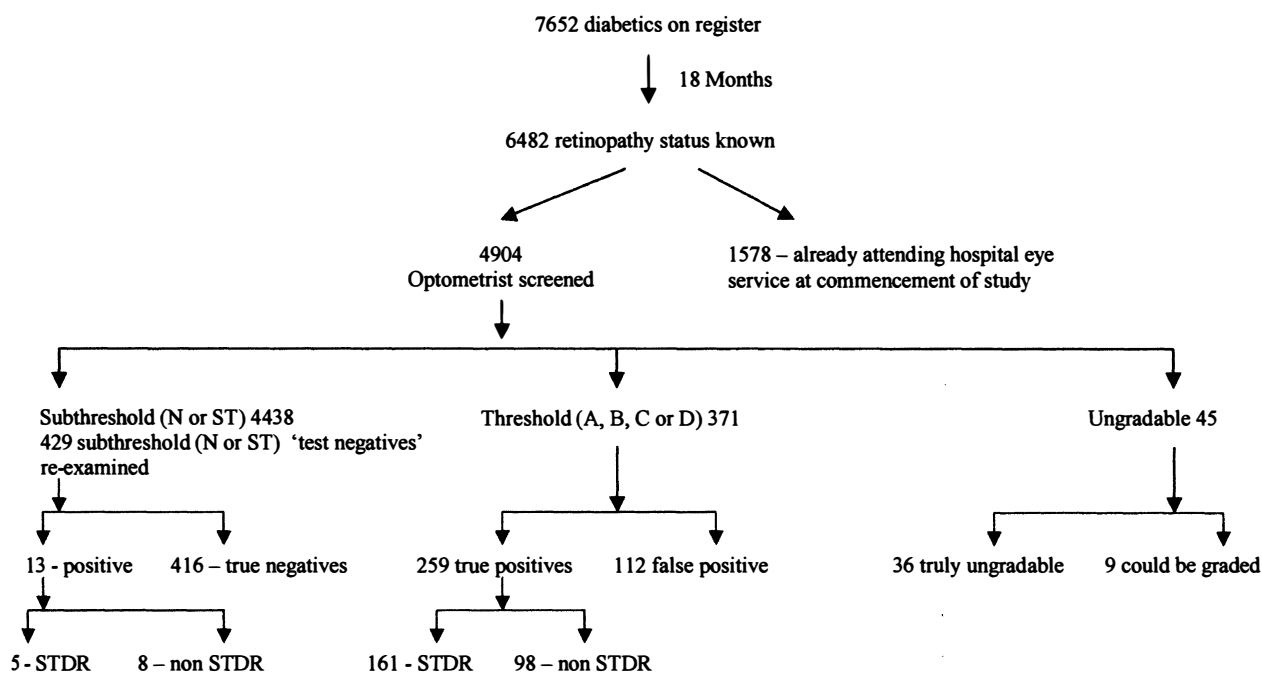

Fig. 1. *Results of screening.*

96%). The likelihood ratio of a positive test was 16.54 (95% CI 14.17 to 19.23) and that of a negative test 0.26 (95% CI 0.20 to 0.32). The technical failure rate was very small: only 9 patients who should have been graded were reported as ungradable, representing 0.2% of all patients screened.

Discussion

Our screening scheme caters for all the people with diabetes in our area, the main exclusion being patients who are already under the care of the hospital eye service. The prevalence of known diabetes in our area was 2.12% (21.2/1000); this is comparable with recent reports from other regions.[13–17] Hands-on training was provided and stringent accreditation criteria applied before optometrists were accredited to perform the screening. While no optometrist formally failed the assessment for accreditation, it is notable that four 'dropped out' during the assessment procedure and hence were not accredited.

The use of a new grading system for use by the optometrists in the screening scheme introduces difficulties when trying to compare our results with those reported by other authors. However, we thought that this was essential. The complexity of the grading systems used in research studies such as the ETDRS,[18] WESDR[9] and EURODIAB[10] rules them out as candidates for use in a mass screening system. The grading systems for diabetic retinopathy that are in use in photographic screening systems, as exemplified by the Welsh Community Diabetic Retinopathy Study[11] and The Liverpool Diabetic Eye Study,[12] are designed for use by expert readers in a centralised facility where all photographs are read. The use of slit-lamp biomicroscopy by a large number of screeners confers some advantages and limitations compared with a photographic system, which need to be considered when choosing a grading system for use in this setting. Slit-lamp biomicroscopy provides a binocular view allowing retinal thickening to be identified. Photographic systems cannot identify retinal thickening and hence use other features such as the presence of hard exudates and haemorrhages within a disc diameter of the fovea as surrogate measures to identify macular oedema; these features form an essential part of the grading systems used for photographic screening but are less important when slit-lamp biomicroscopy is used. Secondly, it is easy to count lesions and measure distances on photographs. However, when multiple fields are being examined on the slit-lamp by moving the eye it is more difficult to count lesions accurately, as individual lesions can easily be counted twice due to the dynamic nature of the examination. Also, it is easier to relate lesions to landmarks such as the vascular arcades than to measure distances when examining the fundus using the slit-lamp. Finally, the use of a large number of screeners in an optometrist screening system means that the system has to be easy to memorise and reproduce in order for it to be robust when used in the community. Taking these features into consideration we devised a new grading system for use in optometrist screening programmes. This system is easy to use, reproduce and memorise, with the emphasis being placed on 'the decision to refer'. It also permits essential information about the patient to be made available to the physician (diabetologist or general practitioner) who essentially needs to know if the patient has no retinopathy, background retinopathy not requiring treatment or more advanced retinopathy needing assessment by an ophthalmologist or treatment. Subdivisions of the grade needing referral to an ophthalmologist were made to enable assessment of the urgency of referral.

The screening test as used in our setting performed well with a sensitivity of 66%, a specificity of 97% and a very low technical failure rate (9/4904, 0.2%). We are therefore confident that our simple grading system is effective and should be easily implementable in other optometrist screening schemes. The aim of screening is to identify cases of STDR. For this, our screening system had a sensitivity of 76% with a specificity of 95%. We believe that there are a variety of reasons for the moderate sensitivity. This was a learning experience for all the optometrists involved, and the emphasis was clearly placed on not missing any STDR. The relatively high false positive rate suggests that the optometrists were being relatively cautious. As experience and confidence amongst the participating optometrists grow, we hope that the false positive rate will reduce. The main cause of false positive grading was drusen that were wrongly thought to be exudates. With increasing experience and regular feedback, the participating optometrists should be able to identify such findings correctly in the future.

Formal studies of the reproducibility of the new grading system have not been undertaken and this is a limitation of our study; however, the high rate of agreement between the optometrists' reported grade and the grade assigned by the ophthalmologist at re-examination would indicate that the screeners were applying the grading criteria consistently. We did not formally mask the re-examining ophthalmologist to the screening report, but the practice was to see the screening report only after the ophthalmologist's grade had been assigned and entered into the database. This may represent a source of review-bias in our study.

A number of optometrist-based screening schemes for diabetic retinopathy are in operation across the country.[18–27] Not all have included specific training, standardised grading systems or clearly defined referral protocols. Minimal research about the effectiveness of these schemes has been undertaken; the number of subjects being re-examined by the 'gold standard' is mostly of the order of 100 only. Method of examination and mydriasis have often been left to the discretion of the screener. The target population in most of these schemes is ill defined and mainly consists of people with diabetes who are under the care of the general practitioner only. This means that 'high-risk' groups are either not examined at all or have examination using direct

ophthalmoscopy by the examining physician, a method which is well known to miss a significant proportion of STDR.[17,28] Our study addresses these issues and shows that an optometrist screening scheme using slit-lamp biomicroscopy is effective.

It is interesting that most reported screening schemes for diabetic retinopathy have a moderate sensitivity and a high specificity. A recent review of diabetic retinopathy screening schemes in the UK included nine studies and separately reported results from 33 subgroups from these studies.[29] Only six of these subgroups reported sensitivity of 90% or higher but 24 reported a specificity of 90% or higher. The emphasis on specificity at the cost of sensitivity can be ascribed to a variety of reasons. The focus of screening programmes has traditionally been to avoid false positive referrals as they cause enormous anxiety to the subject and also lead to inappropriately expensive tests to confirm or disprove the findings. Whilst this is true in the setting of screening programmes such as those used for malignancies or congenital defects, where the emotional effect of having a positive screening test can be devastating and the further tests needed to elucidate the condition have significant side-effects and costs, this may not be an appropriate approach for diabetic retinopathy. Most people with diabetes are reasonably informed about their disease or have access to a multitude of sources of information about the complications of diabetes. They will expect to get retinopathy at some stage and a positive screening test for diabetic retinopathy need not cause disproportionate anxiety provided the results are conveyed in a sensitive manner. Also, effective sight-preserving treatment can be offered, and is widely known to be available, thus further allaying anxiety. The cost implications of false positive referrals remain, but as the 'gold standard' test is an examination by an ophthalmologist without the need for expensive investigations in the non-sight-threatening cases, this cost is not large. It is therefore reasonable to propose that the emphasis in screening schemes for diabetic retinopathy be shifted from ensuring a high specificity to ensuring a high sensitivity, even if that implies a slightly higher false positive referral rate. If the sensitivity of screening schemes is high, it may be possible to increase the screening interval from annual to biannual, thus reducing the inconvenience to people with diabetes and the cost of screening.[30–32] We suggest that future research and screening in this field be directed to achieving a high sensitivity, even if that implies a relatively lower specificity.

Retinal photography has been advocated as the method of choice for a national screening programme for diabetic retinopathy.[4] This modality of screening allows examination to be carried out in a range of settings from clinics to mobile vans, making it useful for community screening using a mobile unit.[17,33–39] Suitably trained readers can then assess the photographs at a central reading facility.[40,41] A study from Liverpool showed fundus photography using three 45° fields, 35 mm film and mydriasis had a sensitivity of 89% (95% CI 80% to 98%) and specificity of 86% (95% CI 82% to 90%) in

assessing 358 people with diabetes. However 14.4% (46 of 320) of photographs were ungradable compared with 2.2% (7 of 320) for direct ophthalmoscopy in the same group after excluding eyes that could not be graded by any method.[12] Most studies have shown a relatively high technical failure rate for fundus photography, as a significant number of films may be ungradable or unobtainable. This has been reported to be between 3.7% to 34%.[2,36,39,42–47] Another study assessed the reading of 35 mm fundus photographs by different groups and reported that general practitioners had a sensitivity and specificity of 79% and 73% respectively, compared with optometrists who achieved 88% and 68% sensitivity and specificity and diabetologists who obtained a sensitivity and specificity 73% and 93% respectively.[11] Others have also reported this variability in performance of different groups of health professionals when reading fundus photographs. A study from Mexico compared the performance of retina specialists with a standardised reading centre and found an overall agreement of only 74%, and concluded that there was a significant discrepancy in the concordance level observed.[48] An advantage of fundus photography is that a permanent record is available and external validation is therefore easy to organise. In comparison with these results, our acceptable high sensitivity, specificity and very low technical failure rate indicate the advantages of slit-lamp biomicroscopy as a screening tool for diabetic retinopathy. External validation of the screening system is difficult to implement when using slit-lamp biomicroscopy, as a permanent record is not available; we did not have an external validation mechanism in place. However, the *de facto* gold standard for fundus examination is slit-lamp biomicroscopy performed by an experienced ophthalmologist, as this is the standard on which treatment decisions are made. If other groups of health care professionals, such as optometrists, can be trained to use this effectively, and a continuing audit process is in place, external validation of the scheme should not be a necessity.

Combined-modality screening has been recommended to increase the sensitivity and specificity of screening.[49] This is most likely to be significant when the sensitivity of at least one of the examination methods being used is low. For single methods that are highly sensitive, the benefit of combining this with an additional screening test is likely to be less significant, whilst increasing the cost. However, if the same operator can be trained to perform both photography and ophthalmoscopy, the additional cost can be minimised and this approach can then be cost-effective.[50] Combined-modality screening can approach the 'Holy Grail' of 100% sensitivity.[51] However, the study that reported this was based on a small number of subjects (144 and 145 in the two phases of the study).[20]

The argument about the best method of screening for diabetic retinopathy will continue. Our study does not directly address that question. A trial directly comparing different forms of screening would address that question, but is unlikely to be feasible because of the large numbers

which will have to be screened using different methods over a long period of time in order to be able to show a difference between different methods, all of which are already known to have an acceptable sensitivity and specificity. Meaningful comparison of sensitivity and specificities reported by different studies is fraught with difficulties due to many factors. These include differences in the populations included, methods of screening used, the grading system used to define a positive screen and the gold standard used in the study. The currently available evidence is insufficient to make specific recommendations on the best method of screening, and therefore this will continue to be dictated according to local circumstances.[29]

In summary, community optometrists with suitable training and accreditation performed well when screening for diabetic retinopathy using slit-lamp biomicroscopy through dilated pupils. This was facilitated by the use of simplified grading and referral criteria. The sensitivity and positive likelihood ratio were high, with a moderate specificity.

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