Comparison of non-mydriatic retinal photography with ophthalmoscopy in 2159 patients: mobile retinal camera study

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Abstract

Objective—To determine whether non-mydriatic Polaroid retinal photography was comparable to ophthalmoscopy with mydriasis in routine clinic screening for early, treatable diabetic retinopathy.

Design—Prospective study of ophthalmoscopic findings according to retinal camera screening and ophthalmoscopy and outcome of referral to ophthalmologist.

Setting—Outpatient diabetic clinics of three teaching hospitals and three district general hospitals.

Patients—2159 Adults selected randomly from the diabetic clinics, excluding only those registered as blind or those in wheelchairs and unable to enter the screening vehicle.

Main outcome measures—Numbers of patients and eyes correctly identified by each technique as requiring referral with potentially treatable retinopathy (new vessel formation and maculopathy) and congruence in numbers of microaneurysms, haemorrhages, and exudates reported.

Results—Camera screening missed two cases of new vessel formation and did not identify a further 12 but indicated a need for referral. Ophthalmoscopy missed five cases of new vessel formation and indicated a need for referral in another four for other reasons. Maculopathy was reported in 147 eyes with camera screening alone and 95 eyes by ophthalmoscopy only ($\chi^2=11.2$; $p<0.001$), in 66 and 29 of which respectively maculopathy was subsequently confirmed. Overall, 38 eyes received laser treatment for maculopathy after detection by camera screening compared with 17 after ophthalmoscopic detection ($\chi^2=8.0$; $p<0.01$). Camera screening underestimated numbers of microaneurysms ($\chi^2=12.9$; $p<0.001$) and haemorrhages ($\chi^2=7.4$; $p<0.01$) and ophthalmoscopy underestimated hard exudates ($\chi^2=48.2$; $p<0.001$).

Conclusions—Non-mydriatic Polaroid retinal photography is at least as good as ophthalmoscopy with mydriasis in routine diabetic clinics in identifying new vessel formation and absence of retinopathy and is significantly better in detecting exudative maculopathy.

Introduction

Despite the availability of effective treatment diabetic retinopathy remains the commonest cause of blindness among the working population of the United Kingdom.^{1,2} The major problem remains that of identifying retinopathy before the onset of visual impairment as treatment at later stages is largely ineffective.³ Retinal screening of all people with diabetes is therefore of great importance.

Several different methods of screening are in current use: ophthalmoscopy by consultants or junior physicians in the setting of a diabetic clinic is the most widely used method³; systems of liaison with ophthalmic opticians have been set up in some districts.⁴ Referral

to an ophthalmologist is an expensive option which is not feasible owing to the large numbers of people with diabetes.⁵ The recent introduction of retinal cameras able to photograph the retina through undilated pupils was initially hailed as a useful method of screening, and several small studies showed its applicability.⁶⁻⁸ The use of non-mydriatic cameras for screening, however, has been subject to much criticism, and an impression of controversy has been created.⁸⁻¹⁰ Any controversy may be more apparent than real as the protagonists have been arguing about practical usefulness of the technique for screening^{6,7} whereas the antagonists have been arguing about poor performance compared with the gold standard technique of fluorescein angiography.^{9,10} Screening techniques cannot be expected to perform as well as detailed investigative techniques but may appropriately be compared with each other. There was therefore a need for a single clearly defined question to be answered before non-mydriatic retinal photography could be accepted as a screening tool: Is non-mydriatic retinal photography as good as ophthalmoscopy with mydriasis when performed in the setting of a routine clinic?

To answer this question in a generally applicable manner it was necessary to perform the comparison in a large number of patients in more than one clinic. A mobile camera unit was designed and used to evaluate screening methods in three clinics in district general hospitals and three in teaching hospitals over two years.

Patients and methods

PATIENTS

Table I shows the characteristics of the study population. A total of 4312 eyes in 2159 patients were photographed. The patients were selected at random from the clinic list; only those in wheelchairs or who were registered as blind were excluded, and hence patients aged 12 to 89 years and with a duration of diabetes ranging from 0 to 60 years were studied. Most were white.

THE MOBILE UNIT

A transit ambulance donated by Northern Regional Health Authority was converted to allow transverse mounting of a Canon CR3-45NM camera on a motorised table immediately behind the driving compartment. No suitable commercially available vibration proof mounting for the camera was available, and a device was custom built, consisting of high density foam blocks held within a steel frame bolted to the floor. In transit the camera was allowed to float on the foam pads and in operation it rested on the motorised table. This device has proved successful in that the unit has been operating for three years and a distance of about 15 600 km has been driven without damage to the camera. A blackout curtain was placed to separate the camera from a small waiting area containing two bench seats. All windows were covered and 40 watt red lighting was installed. An electrical supply was

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*Reference range 5.0-7.5%.

Schnellen chart (Rayner Optical Company) and then one eye per patient was photographed, allowing time for the consensual response to fade before the second eye was photographed. Polaroid 779 film was used throughout the study. Each batch of four patients was dealt with in about 20 minutes; thereafter they returned to the waiting room and mydriatic drops were instilled. Ophthalmoscopy was performed as part of the routine consultation by the doctor who would ordinarily have seen the patient. A standard form was completed, which included sketches of each retina (figure). No specific training in funduscopy was given. Biochemical data were entered on to the form as soon as they were available, and the form was collected by the photographer.

The retinal photographs were not seen by staff in the clinic but were retained in the screening unit. They were subsequently reported in batches by one of three consultant physicians using a similar proforma to that in the figure but including scores for "poor film" and "macula not visualised." A poor film was defined as one in which the entire area of retina photographed could not be clearly seen and macula not seen as a film in which the area within one disc diameter of the macula lacked clarity. The second category was adopted as films taken through a constricted pupil tend to exhibit a characteristic darkness around the macula.

Criteria for referral were agreed with the local ophthalmologists as: (a) presence of new vessels; (b) preproliferative retinopathy; (c) exudative maculopathy; and (d) presence of lesions within one disc diameter of the macula.

In a preliminary exercise 30 films were reported by all three observers. Counts of haemorrhages and hard exudates agreed to within five lesions in 23 and 22 cases respectively, but one observer consistently reported more microaneurysms. Of three cases of maculopathy, one was correctly classified by all observers and two were identified by two observers. This exercise allowed agreement on definition and terminology. To allow assessment of observer consistency during the last 12 months of reporting of the films in the study eight unmarked "quality control" films were inserted into batches for reporting on five occasions each per observer. The mean intraobserver consistency of counting lesions to within one band (<1 , 2-5, 6-10, 11-20, and >21) was 89.2% for haemorrhages, 90.8% for hard exudates, and 80.0% for microaneurysms. When maculopathy was present the mean detection rate was 87.0% and when new vessels were present it was 100%.

A computer database was constructed from the paired forms for each patient and was used to derive information on the comparability of the two methods. Information on referral to an ophthalmologist and any subsequent treatment was obtained from clinical

Standard form for recording ophthalmological findings and patient data

records. In those patients in whom potentially serious retinopathy had been identified by camera screening but had been missed clinically the consultant concerned was notified to allow the patient to be referred. The sensitivity of detection for each technique was defined as true positives/(true positives+false negatives). Specificity of detection was defined as true negatives/(true negatives+false positives). Data are presented as mean (SD) and statistical analysis was performed with McNemar's test.¹¹

Results

NEW VESSELS

Forty eyes with definite new vessel formation were detected in the study (table II), of which 17 were detected by both techniques, 14 were missed by camera screening, and nine were missed by ophthalmoscopy ($\chi^2=1.2$; NS). In the 14 cases of apparent failures of detection by camera screening nine of the films were scored as poor, advanced diabetic eye disease was reported in 10 films without specific identification of new vessels, and no film had been obtained for one eye owing to advanced disease changes. Two cases of true failure of detection by camera screening occurred, this being defined as overall failure of the technique to trigger referral in the presence of new vessel formation. In one case new vessels were clearly visible on reviewing the film, the failure having occurred at the time of reporting, and in the other no new vessels could be seen. Of the nine eyes in which new vessel formation was missed by ophthalmoscopy, four were scored as requiring referral for other reasons and in five the vessels had been missed for no obvious reason.

Overall sensitivity and specificity cannot be calculated as the study was designed as a comparison and did not include a gold standard. However, within the population reported to have new vessels by any method (n=118 eyes) the sensitivity of the camera in detecting new vessels was 65.0% compared with that of 77.5% for ophthalmoscopy. The specificity of diagnosis of

new vessel formation with the camera was 60.3% and that for ophthalmoscopy was 39.7%.

The presence of new vessels arising from the optic disc was detected and confirmed in 16 eyes. In 10 new vessels were detected by both methods, in three they were missed by the camera, and in three they were missed by ophthalmoscopy.

MACULOPATHY

Maculopathy was reported in 208 patients (308 eyes) by either or both techniques (table III). The camera detected maculopathy not identified with ophthalmoscopy in 147 eyes compared with 95 eyes in which maculopathy was detected by ophthalmoscopy alone ($\chi^2=11.2$; $p<0.001$). A further 66 eyes were identified as having maculopathy by both techniques, of which 49 were confirmed as having maculopathy and 33 received laser treatment. Thirty eight eyes received laser treatment because of camera screening alone compared with 17 eyes because of screening by ophthalmoscopy alone ($\chi^2=8.0$; $p<0.01$). For 29 eyes with maculopathy reported on camera screening a referral for specialist opinion was not made, and hence these data underestimate the performance of camera screening.

The designation of maculopathy at screening was confirmed by an ophthalmologist as being true exudative maculopathy in 45% of eyes (n=66) on referral after camera screening alone and in 39% of eyes (n=29) on referral after ophthalmoscopy alone. The rest of the cases were accounted for by lesions being present but not close enough to the macula to be classed as maculopathy and also by degenerative changes, including drusen degeneration. Among the population reported to have exudative maculopathy (n=308), camera screening exhibited a sensitivity of 74.2% compared with 57.4% for ophthalmoscopy; the respective specificities were 55.3% and 67.0%. Confirmation of diagnosis of exudative maculopathy was not always followed by laser treatment, and this reflected varying degrees of severity as well as differing ophthalmological practices. Of the 66 eyes in which maculopathy was detected by both techniques (table III), six exhibited changes too advanced to benefit from laser treatment.

BACKGROUND RETINOPATHY

In all, 2558 eyes (59.3%) or 1066 patients (49.4%) were reported as free of any diabetic lesion by both techniques. Camera screening alone reported 3046 (70.6%) eyes as normal and ophthalmoscopy alone 3111 (72.1%). Table IV shows the reporting of microaneurysms, haemorrhages, and hard exudates by each technique. Camera screening underestimated by more than 10 the numbers of microaneurysms ($\chi^2=12.9$; $p<0.001$) and haemorrhages ($\chi^2=7.4$; $p<0.01$) more often than did ophthalmoscopy, but the reverse was true for hard exudates ($\chi^2=48.2$; $p<0.001$).

GRADE OF STAFF

Table V shows the number of eyes seen by each grade of staff for which a discrepancy of more than 10 lesions was reported. All grades except senior house officers tended to report more microaneurysms and haemorrhages with ophthalmoscopy than photography, and all grades tended to report fewer

TABLE II—Numbers of eyes with new vessel formation reported with retinal camera screening alone or ophthalmoscopy alone, or both, and numbers in which finding was confirmed by ophthalmologist. (To reflect overall management outcome for each technique numbers of eyes scored for referral without mention of new vessels and of those with new vessel formation which were not referred for ophthalmological assessment (true missed new vessels) are included)

Technique	Eyes with reported new vessels	Eyes with confirmed new vessels	Eyes scored for referral but new vessels not seen	Eyes with missed new vessels
Ophthalmoscopy alone	61	14	5	4
Camera screening alone	40	9	12	2
Ophthalmoscopy and camera screening	17	17	—	—
Total	118	40		

TABLE III—Numbers of eyes with maculopathy reported with retinal camera screening alone or ophthalmoscopy alone, or both, and numbers in which finding was confirmed by ophthalmologist, according to treatment by photocoagulation. (Numbers for which screening diagnosis was not confirmed by ophthalmologist and those not referred for any reason are also shown)

Technique	Total	Maculopathy confirmed and treated	Maculopathy confirmed but not treated	Maculopathy not confirmed	Not referred
Ophthalmoscopy alone	95	17	12	55	11
Camera screening alone	147	38	28	52	29
Ophthalmoscopy and camera screening	66	33	16	17	0

TABLE IV—Relative performance of each technique for specific lesions. Figures are numbers of eyes for which one technique reported 3-10 or over 10 more lesions than the other. Numbers represent previously defined computer banding of counts of lesions

Discrepancy	Microaneurysm		Haemorrhage		Hard exudate	
	Camera screening	Ophthalmoscopy	Camera screening	Ophthalmoscopy	Camera screening	Ophthalmoscopy
3-10	236	267	102	117	157	116
>10	65	113	30	55	124	36

TABLE V—Effect of grade of observer on number of eyes for which a discrepancy of >10 lesions was reported between camera screening and ophthalmoscopy

Grade of observer	No of eyes	Microaneurysms		Haemorrhages		Hard exudates	
		Camera screening	Ophthalmoscopy	Camera screening	Ophthalmoscopy	Camera screening	Ophthalmoscopy
Consultant	1460	27	49	15	30	50	17
Clinical assistant	502	5	3	1	6	6	3
Senior registrar	652	5	22	5	5	17	7
Registrar	1178	18	33	6	13	37	7
Senior house officer	420	10	6	3	1	14	2

hard exudates with ophthalmoscopy (ratios of camera reporting to ophthalmoscopy reporting more: 2.9, 2.0, 2.4, 5.3, 7.0 for consultants, clinical assistants, senior registrars, registrars, and senior house officers respectively).

The percentage of the total number of important reported lesions corroborated by the camera report varied according to grade of staff. For maculopathy confirmation occurred in 62.9% for consultants, 44.4% for clinical assistants, 50.0% for senior registrars, 35.6% for registrars, and 25.0% for senior house officers. For new vessels, confirmation occurred in 39.1% for consultants, 23.1% for clinical assistants, 22.2% for registrars, and 25% (n=1) for senior house officers. No cases of new vessel formation occurred among those patients seen by senior registrars.

POOR FILMS

A total of 433 films (10.0%) were reported as poor, of which 93 (2.2%) were associated with cataracts and 196 (4.5%) with small pupils. The presence of small pupils was scored by the operator before photography, and hence these poor films were potentially avoidable, leaving 5.5% as unavoidable poor films. Two hundred and eight films were scored as macula not seen, 21 of which were associated with cataracts and only 61 of which with small pupils. This appearance was seen predominantly (71%) in right eyes, reflecting the unplanned tendency to photograph left eyes first and hence the residual consensual response in the other eye. Judgment of when the consensual response had faded adequately was thus less easy than had been predicted. Small pupils were scored only before any photography and hence were not reported as effects of consensual pupillary constriction.

Discussion

The results of this study indicate that non-mydratric Polaroid retinal photography is at least as good as funduscopy with mydriasis performed under routine diabetic clinic conditions in detecting new vessel formation. It is superior in detecting maculopathy. These conclusions were reached despite the doctors in the clinic knowing that their performance was being evaluated and despite the photographs being assessed in large batches as an extra late evening duty by the three observers. However, non-mydratric photography cannot be assumed to be automatically superior as it is dependent upon the skill of the camera operator. It is a simple matter to take correctly aligned, focused retinal photographs of a normal eye, but experience is required to deal with cataracts, disordered fundi, and people less able to comply with instructions. The proportion of technically poor films in this study was lower than the 17.3% reported by Jones *et al*, and this may reflect their use of several photographers without a special interest in retinal screening.⁹ In routine practice, now that the study has been completed, the number of poor films has been halved because of use of mydratric drops before photography if pupils are noted to be too small by the camera operator. In addition, analysis of data from the study showed a need for particular care in allowing the consensual response to

fade completely, and the number of films exhibiting a shadow in the region of the macula has subsequently fallen. In our current practice use of a short acting mydratric (tropicamide) is indicated only in about 5% of patients. Although routine mydriasis may be argued to produce better photographs, the use of such eye drops is not popular with patients, especially those who will return to work after being screened.

The relatively poor performance of all grades of doctor in detecting maculopathy is interesting and was noted in other studies.³ Only 49 eyes were treated for maculopathy as a result of ophthalmoscopy whereas 70 were treated as a result of photography. This difference is all the more striking as for some eyes reported as exhibiting maculopathy a referral for an ophthalmological opinion was not made, maculopathy not being an outcome parameter in the original protocol. The macular region is sometimes difficult to examine adequately by ophthalmoscopy because of reflection of light and discomfort in the patient. In addition, lesions lateral to the macula may be missed because the examiner's head needs to move across the subject's face, disturbing visual fixation. The underreporting of hard exudates by ophthalmoscopy is probably related to this as these lesions typically occur in the posterior pole of the eye. Qualitative inspection of the diagrams sketched by the doctors in the clinic suggested that the excess of haemorrhages and microaneurysms reported by ophthalmoscopy was a consequence of full examination of the retina nasal to the optic disc, a characteristic site for these lesions. It seems likely that many doctors regard the optic disc as the anatomical centre of the retina and use it as a reference point in quartering the retina in the search for lesions. This carries the inevitable consequence that the retina lateral to the macula (one half of the total retinal area) will be examined poorly.

Analysis of the number of confirmations of important ophthalmoscopic findings on camera screening suggests that consultants performed marginally better than senior registrars, clinical assistants, and registrars. Senior house officers performed notably worse than other non-consultant staff. This did not bias the comparison between the two techniques as fairly small numbers of examinations were performed by senior house officers, and it must be considered that their participation in clinic screening is widespread in the United Kingdom. Experience did not confer infallibility, five of the nine cases of missed new vessel formation by ophthalmoscopy concerning consultants. The variability in opinions reported for ophthalmologists suggests that the technique cannot be regarded as a gold standard even in expert hands.³

It is apparent from the results in tables II and III that in only a proportion of patients referred as having possible new vessel formation or exudative maculopathy was the condition confirmed on subsequent referral to an ophthalmologist. The specificity of ophthalmoscopy was particularly poor for detecting new vessels (39%), but it must be considered that this may reflect awareness of being assessed on the part of the clinic doctor as well as relative unfamiliarity with recognition of new vessels. Referral of such false positive findings will tend to increase the real cost of a

screening programme, but setting referral criteria for clinical practice must reflect both the skill of the screener so that the rate of missed lesions is low and also the capacity of the local ophthalmology department.

The routine measurement of visual acuity as part of any screening programme must be emphasised. Macular oedema may be present without exudate formation and hence would be undetectable on a single film as opposed to stereo photographs of the fundus.¹² A fall in visual acuity is a most important indicator of macular oedema, and, although no provision for assessing serial change in visual acuity was incorporated into this study, it must be considered an essential part of establishing a clinical service.

One of the major concerns about non-mydratric photography has been that important lesions may lie outside the 45° field examined and may be missed.⁸ This was not observed in the 4312 eyes examined in this study, but none the less it remains a theoretical source of error for this screening technique. A second major concern of critics of the technique was that new vessel formation would be missed, the new vessels being anterior to the plane of photographic focus. This was found not to be the case, new vessels being missed in only two eyes other than when advanced diabetic eye disease had made photography difficult. In such cases new vessels were always evident from inspection of the photograph, and most of the patients concerned were already under ophthalmological review. We observed during initial evaluation of the camera that new vessels arising from the disc may sometimes be hidden owing to back reflection of light from the disc, and because of this we carried out a small initial evaluation of how well the technique performed on a series of 12 patients about to have laser treatment.¹³ New vessels arising from the disc were not apparent in one case. In the main study disc new vessel formation was missed in equal numbers of patients by camera screening and by ophthalmoscopy, 10 cases being correctly detected by both.

For a limited period before the study started and after it finished an evaluation of the impact of availability of Polaroid photographs in the clinic was possible. The educational effect for both junior staff and senior staff of seeing the disposition of lesions missed by initial ophthalmoscopy was considerable. Teaching of ophthalmoscopy to medical students in the clinic was revolutionised. In some patients reassurance was provided by showing the actual appearance of lesions previously imagined to be worse whereas in others the vital importance of need for specific treatment or tighter control was graphically clarified. The utility of a photographic record of previous retinal appearances in the clinical notes was greater than expected, allowing a more confident decision to refer or not. The darker, pigmented fundi of Indian patients were shown to be examinable by non-mydratric photography just as effectively as in white patients.¹⁴

The cost of this method of screening for and recording diabetic retinopathy must be considered. The Polaroid film alone costs about £1 per pair of eyes. Depreciation on the capital cost of the camera (£10 500 over six years); salaries of the camera operator and the driver; and vehicle maintenance, insurance, and petrol costs must be taken into account. If a modest weekly

throughput of 150 patients and a 48 week year is assumed the total cost per patient is £2.92. Use of Polaroid retinal photography is often discussed in relation to screening by ophthalmic opticians. The cost to the Department of Health is £10 for screening by an ophthalmic optician. Assessment of the cost of screening in the hospital clinic must take account of the time necessary to perform comprehensive funduscopy with mydriasis and of maintaining adequate darkroom facilities. Limitation of time and facilities has fuelled the search for alternative methods of screening.

In conclusion, non-mydratric retinal photography is as good as funduscopy with mydriasis in routine clinics in detecting new vessel formation but is superior in detecting maculopathy. The educational effect and audit function of having Polaroid photographs available in the clinic make the technique particularly useful for centres concerned with postgraduate and undergraduate training. Non-mydratric retinal photography may be used purely as a screening technique by doctors who do not perform ophthalmoscopy often enough to maintain the skill, such as those in general practice.¹⁵ However, these conclusions apply only when the technique is used by a trained operator.

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