
Screening for Diabetic Retinopathy in a Clinical Setting: A Comparison of Direct Ophthalmoscopy by Primary Care Physicians with Fundus Photography

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Background. Type II diabetes mellitus is a major health problem among Native Americans, and diabetic retinopathy is a frequent complication of this disease. Screening for retinopathy can identify early disease and prevent major vision loss, but the most cost-effective screening method has not yet been determined.

Methods. In a rural clinic that served more than 400 Native Americans with diabetes, we compared the accuracy of referrals made based on two screening methods: ophthalmoscopy by trained primary care physicians and seven-view nonstereoscopic, mydriatic fundal photography read by two general ophthalmologists and a retinal specialist. Patients in whom abnormal findings were detected by either screening method were then referred to a general ophthalmologist for further evaluation.

Results. Two hundred forty-three examinations were performed and 83 referrals made. Both screening methods had high sensitivity for referring patients with retinopathy that required treatment or follow-up

sooner than 1 year (100% for direct ophthalmoscopy by primary care physicians, 94% for the general ophthalmologist photography readers, and 100% for the retinal specialist reader). The calculated costs of screening by direct ophthalmoscopy and by retinal photography were 64% less and 44% to 35% less, respectively, than the cost of yearly ophthalmological examinations by ophthalmologists.

Conclusions. Careful screening for treatable diabetic eye disease by trained primary care physicians proved to be a clinically acceptable, cost-effective strategy. Screening methods for diabetic retinopathy should be evaluated based on the absolute sensitivity, specificity, and predictive values of their ability to correctly refer patients rather than their diagnostic accuracy.

Key words. Diabetes mellitus; diabetic retinopathy; mass screening; cost-benefit analysis; ophthalmology.
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Diabetes mellitus is a major cause of morbidity and mortality among Native Americans and Alaska Natives.^{1,2} Almost all the diabetes in these populations is

type II, non-insulin-dependent diabetes mellitus (NIDDM). A frequent and potentially catastrophic complication of diabetes mellitus is diabetic retinopathy.^{3,4} Diabetic retinopathy is the most frequent cause of new blindness in the United States among people 20 to 74 years of age.⁵ Timely treatment by photocoagulation therapy can prevent major vision loss. To be effective, however, it must be done before symptoms develop.^{6,7} Thus, screening of asymptomatic patients is an essential element of prevention.⁸ Furthermore, such screening can be cost-effective.⁹⁻¹²

Various screening techniques for retinopathy have been studied, including direct ophthalmoscopy through dilated or undilated pupils; indirect ophthalmoscopy; and stereoscopic or nonstereoscopic retinal photography through dilated or undilated pupils.¹³⁻²⁸ It has been

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suggested that seven-field stereoscopic fundus photography or fluorescein angiography should be used as the reference standard with which the effectiveness of screening methods can be compared,²⁹ with most experts currently supporting the use of the former. However, indirect ophthalmoscopy by specially trained personnel has sometimes been used to make the definitive diagnosis for practical reasons.^{14,24,25} Recently, the American College of Physicians, the American Diabetes Association, and the American Academy of Ophthalmology concluded that stereoscopic fundus photography is the most sensitive screening technique, but acknowledged that this method is not widely available and may not prove to be as sensitive outside the research setting.⁸ These groups concluded: "At present, therefore, yearly dilated ophthalmoscopic examination seems the best approach." They also stated that nonmydriatic fundus photography has been proposed for mass screening and appears to be as accurate a screening method as dilated ophthalmoscopy. Similarly, a European working group³⁰ recently concluded that "direct ophthalmoscopy through dilated pupils is the recommended test to screen for diabetic retinopathy, because it is inexpensive, efficient and rapid." This group also cautioned that "it should always be performed by a trained observer." No study to date has compared screening by dilated ophthalmoscopy performed by primary care physicians with that by nonstereoscopic, mydriatic retinal photography in an actual clinical setting.

Methods

The Yakima Indian Health Center (YIHC) is an outpatient facility located on the Yakima Indian Reservation in Toppenish, Washington. The YIHC provides services to approximately 12,700 Native Americans and Alaska Natives. More than 400 of these patients are diabetic. Each year the clinic has more than 43,000 patient encounters, of which approximately 18,000 are physician care visits. Since November 1985, as a part of its diabetes care program, the YIHC has conducted special monthly diabetic eye screening clinics during which primary care physicians perform dilated retinal examinations on diabetic patients.

In collaboration with the Centers for Disease Control, the Washington Diabetes Control Program established the Yakima Diabetic Eye Screening Project (YDESP) in Yakima County in October 1986. This project provided eye screening using retinal photography to all interested diabetic patients at six sites in Yakima County. One of the six sites was the YIHC, which differed from the other five sites in three significant ways.

First, the patient population was Native American. Second, the YIHC used outreach efforts to ensure the attendance of as many of the patients needing screening as possible. And third, the retinal photography screening provided by the YDESP was added to YIHC's direct ophthalmoscopy screening program. The concurrent use of these two screening methods provided an opportunity to compare them.

Before the combined YIHC-YDESP study began, the four YIHC primary care physicians (with 1 to 30 years' experience) received a 2-hour update about diabetic retinopathy and their role as primary screeners for this disease. A retinal specialist from the University of Washington participating in the YDESP gave the presentation, which included slides of normal and diseased fundi and a discussion of which findings warranted patient referral to an ophthalmologist. The training emphasized that the physician should not try to differentiate between retinopathy that required photocoagulation treatment and retinopathy that required only closer observation. Rather, physicians should refer every patient with marked retinopathy to an ophthalmologist for further examination.

The YIHC diabetic screening clinic staff obtained the following clinical information from each patient included in the study: duration of diabetes mellitus, results of previous eye examinations, previous eye care, and ophthalmologic symptoms. This information was recorded on a clinical data form. The patient's blood pressure and visual acuity were checked and noted on the form. Then the patient's pupils were dilated, and one of the primary care physicians performed direct ophthalmoscopy. If this physician found marked retinopathy (ie, retinopathy with more than just rare background changes, preproliferative retinopathy, proliferative retinopathy, or signs suggestive of macular edema), he or she referred the patient to one of several local board-certified general ophthalmologists (hereafter called the *referral ophthalmologist*) for full examination and treatment, if indicated. During the YIHC clinic, every patient's chart was available for review by the physician doing the examination. If the physician found information in the patient's chart about previous screening, diagnostic ophthalmologic examinations, or previous photocoagulation treatment for retinopathy that had not been listed, the information was added to the form. The physicians did not have access to retinal photographs either during their examination or when giving their disposition for the patient.

After undergoing direct ophthalmoscopy, a trained camera technician measured the patient's intraocular pressure by applanation. The technician took nonstereoscopic photographs of each eye using a variable angle

portable mydriatic retinal camera. During a 5-month interval early in the project, the number of photographs taken of each eye was reduced from seven to two. Because the proportion of unreadable photographs was high, however, the number was increased again to seven for the remainder of the project. One of two local board-certified general ophthalmologists (hereafter referred to as the *general ophthalmologist readers*) reviewed each set of retinal photographs. In the first 21 months of the project, the participating retinal specialist (hereafter referred to as the *retinal specialist reader*) at the University of Washington also read each set of photographs. The two general ophthalmologist readers and the retinal specialist reader all followed the same protocol, but were blinded to each other's findings. After reviewing the clinical data form and examining the photographs, the general ophthalmologist reader and the retinal specialist reader each made his assessment and disposition for that patient. These recommendations were "routine eye care," "appropriate referral," "urgent referral," or "repeat photographs." None of the photography readers had access to the physicians' screening assessments or dispositions.

The photography readers' assessments and recommendations were then returned to the primary physician and, if indicated by either report and if the patient had not already been referred, the patient was sent to a referral ophthalmologist. If either the general ophthalmologist reader or the retinal specialist reader found the photographs "unreadable," and the other screeners had concluded that the patient's fundi were normal or had only "mild background retinopathy," the patient was not referred.

Patients were referred for further examination by an ophthalmologist when either of two conditions occurred: (1) any screener found a positive result, or (2) another serious problem such as cataracts or unexplained decreased vision was detected. Thus, all patients with marked findings on screening, as well as numerous patients with negative screening results, were referred to an ophthalmologist for further examination. Of these patients only those requiring photocoagulation therapy underwent subsequent reference-standard examinations (ie, seven-field stereoscopic retinal photography or fluorescein angiography²⁹).

All retinal photography readers recommended "appropriate referral" when a photograph was judged "unreadable." (If retinal photography is the sole screening method, this is the most prudent action.) Therefore an "unreadable" result was recorded as a recommendation for referral.

When the 33-month study was complete, the following data were collected for analysis: (1) the screening diagnosis and actual disposition made by the primary

care physician doing direct ophthalmoscopy; (2) the screening diagnoses and dispositions made by the photography readers; and (3) the final diagnosis and recommendation of the referral ophthalmologist. The diagnosis used for our analysis was the most serious diagnosis made for either eye.

The study calculated the sensitivity of each of the two screening examinations, defined as the test's ability to correctly refer patients for evaluation for diabetic retinopathy. Because the purpose of the study was to compare the ability of each screening test to correctly refer patients rather than the ability to diagnose accurately, we defined a "positive screening test" as one in which the patient was referred for diabetic retinopathy, and a "negative screening test" as one in which the patient was not referred for diabetic retinopathy. We defined "positive diagnosis" as one in which "the referral ophthalmologist's examination found either significant background retinopathy with a planned recheck in less than 12 months, or preproliferative retinopathy, or proliferative retinopathy, or macular edema." We defined "negative diagnosis" as one in which "the referral ophthalmologist's examination found either no significant retinopathy, or only mild background changes with planned recheck in 12 months."

Because most patients with negative results (ie, no diabetic retinopathy) in all three screeners' tests were not referred to an ophthalmologist, we modified the calculations of sensitivity, specificity, and negative predictive value from the standard methods. We calculated both sensitivity and specificity by assuming that no patient without a positive result of a screening examination by either method would have had a positive diagnosis if examined by a referral ophthalmologist at the time. However, one or more of the patients with negative results in all screening examinations could have had serious retinopathy requiring frequent rechecking or laser treatment. One or more such patients would have lowered the rates of sensitivity, specificity, and negative predictive values. The formula for positive predictive value, however, does not include "false negatives," and thus is unaffected by this assumption.^{31,32} Therefore, we labeled the three values obtained the "estimated maximum sensitivity," "estimated maximum specificity," and "estimated maximum negative predictive value."

Statistical tests included Student's *t* test and Fisher's exact test. All statistical tests were double-tailed. Exact 95% confidence intervals (CI) of proportions were calculated by TRUE Epistat.³³ The estimations of costs were based on average charges according to the American Academy of Ophthalmology and salaries of the YIHC personnel at the time of the study. The actual costs of taking the retinal photographs and having them read

Table 1. Results of Screening Examinations for Diabetic Retinopathy

Screening Examination Outcome	No. of Examinations (%) (N = 243)
All examinations were negative	167 (69)
Not referred (no diagnostic results available)	150
Diagnostic results available (referred for other reasons)	17
At least one examination was positive	76 (31)

were obtained from the Washington Diabetes Control Program staff.

Results

From November 1986 to July 1989, 188 diabetic patients made a total of 243 visits during these special eye screening clinics (Table 1). Because the study period was longer than 2 years, some patients came to the clinic more than once. One patient made three visits, 53 patients made two, and 134 patients made one. During each visit, the patient received both direct ophthalmologic and retinal photography screening. In 76 of the 243 visits, at least one of the screeners identified marked retinopathy. Seventeen additional visits resulted in a referral to evaluate findings other than diabetic retinopathy. Of the 93 referrals made, 10 patients were lost to follow-up. Thus, 83 referral visits were completed.

The mean duration of diabetes at the time of the screening was 14.0 years for those in whom diabetic

retinopathy was ultimately diagnosed, compared with 7.9 years for those without retinopathy ($P < .001$). Fifty-eight percent of those with retinopathy were women, and 55% of those without retinopathy were women.

The data from all screening examinations are given in Table 2. Because we found that two photographs were not adequate for effective screening, only the data for screening examinations in which seven views of each retina were photographed were used in the analysis. Since the number of photographs did not affect the primary care physicians' examinations, data from all direct ophthalmoscopic examinations were included. The summary measures of sensitivity, specificity, and predictive value are given in Table 3.

Based on direct ophthalmologic examination, the primary care physicians made 19 referrals for 17 patients (two patients were seen on two separate occasions) in whom one of the referral ophthalmologists diagnosed significant retinopathy. Six of these referrals resulted in the patient undergoing photocoagulation therapy, and the other 13 resulted in the patient returning for a follow-up examination in less than 12 months. This screening method referred all patients ultimately diagnosed as having significant retinopathy. The estimated maximum sensitivity of the direct ophthalmologic screening by primary physicians was 100% (19/19); the estimated maximum specificity was 93% (198/214). The estimated predictive value of a positive screening test was 54% (19/35); the estimated maximum predictive value of a negative screening test was 100% (198/198).

The general ophthalmologist readers referred 16 of

Table 2. Accuracy of Two Methods of Screening for Diabetic Retinopathy as Determined by a Subsequent Diagnostic Examination by an Ophthalmologist

Result of Screening Examination	Result of Diagnostic Examination	Ophthalmoscopy, Primary Care Physicians (n = 233)*	Retinal Photography	
			General Ophthalmologist Readers (n = 169)*	Retinal Specialist Reader (n = 93)*
Positive or unreadable (referred)	Positive (earlier follow-up or laser treatment)	19	16	13
	Negative (routine annual follow-up)	16	27	29
Negative (not referred)	Positive (earlier follow-up or laser treatment)	0	1	0
	Negative (routine annual follow-up)	198 (150+)	125 (99+)	51 (43+)

*Patients who did not complete the referral were not included in the analysis.

†Number of patients in this cell for whom all three screening examinations were negative, who were not referred for other reasons, and who therefore did not undergo an examination by a referral ophthalmologist. They were assumed not to have significant diabetic retinopathy for purposes of calculating estimated maximal values of the various measures of accuracy.

Table 3. Test Characteristics of Two Screening Methods for Diabetic Retinopathy

Screening Method (No. of Examinations)	Estimated Maximum Sensitivity, % (95% CI)	Estimated Maximum Specificity, % (95% CI)	Estimated Positive Predictive Value, % (95% CI)	Estimated Maximum Negative Predictive Value, % (95% CI)
Direct ophthalmoscopy screening by primary physicians (N = 233)	100*	93 (88-96)	54 (37-71)	100*
Retinal photography screening by General ophthalmologist (n = 169)	94 (71-100)	82 (75-88)	37 (22-53)	99 (96-100)
Retinal specialist (n = 93)	100*	64 (52-74)	31 (18-47)	100*

*Unable to calculate confidence intervals for proportions of 100%.

the 17 patients in whom referral ophthalmologists subsequently diagnosed significant retinopathy. The one patient missed was later diagnosed as having moderate background retinopathy requiring follow-up examination in less than 12 months. The reader who failed to make the referral had read this set of photographs as depicting mild background retinopathy that did not warrant referral; thus, a serious error was not made. The general ophthalmologist readers reported that 5% (9/169) of the sets of photographs were unreadable. The estimated maximum sensitivity of the screening by fundus photography with general ophthalmologist readers was 94% (16/17), the estimated maximum specificity was 82% (125/152), the estimated positive predictive value was 37% (16/43), and the estimated maximum negative predictive value was 99% (125/126).

The retinal specialist reader was located 150 miles from the clinic site and was unable to participate for the full duration of the study. He therefore read only 93 sets of photographs. He accurately recommended referral of 13 patients who were ultimately diagnosed as having significant retinopathy (the other 6 of the 19 visits in which patients were referred for significant retinopathy were not represented among the 93 sets of photographs). The retinal specialist reported that 9 (10%) of the 93 sets of photographs he reviewed were unreadable. The estimated maximum sensitivity of the screening by the retinal specialist reader was 100% (13/13), the estimated maximum specificity was 64% (51/80), the estimated positive predictive value was 31% (13/42), and the estimated maximum negative predictive value was 100% (51/51).

We calculated costs of screening and diagnosing 100 patients by each of these methods. The projected costs were \$8800 for referring all patients annually for oph-

thalmologists' full examinations, \$4942 to \$5734 for screening by retinal photography, and \$3132 for direct ophthalmoscopic screening by primary providers. These estimates included personnel and material costs and the costs of full diagnostic examinations for those referred. They did not include transportation, training, equipment, or other direct and indirect costs.

Discussion

The results of our practice-based study suggest that dilated ophthalmoscopic screening by primary care physicians may be as accurate as and more cost effective than nonstereoscopic retinal photography through a dilated pupil.

An earlier study questioned the ability of various providers to diagnose various grades of diabetic retinopathy accurately.³⁴ Screening tests for any disease, however, are judged on their accuracy in referring patients for further diagnostic testing by a specialist, not their accuracy in diagnosing a specific disease. A screening test must differentiate those patients who need more definitive testing from those who do not. Baker et al¹³ alluded to this need for "correct referral of patients" rather than "correct identification of fundus abnormalities." Just as the Papanicolaou test does not accurately differentiate between CIN II and CIN III, the stool guaiac test between colon cancer and other causes of intestinal bleeding, and the Venereal Disease Research Laboratory between syphilis and biological false positives, a screening test for diabetic retinopathy need not differentiate accurately between various grades of retinopathy. Screening tests must be sensitive enough to identify all patients with disease needing further evaluation, however, and

specific enough to eliminate from further evaluation most patients without disease. Furthermore, the predictive values of the second, more definitive evaluation are higher if preceded by effective screening.

The referral definition of screening used in this study is especially relevant for research on the sensitivity, specificity, and predictive values of different methods of screening for diabetic retinopathy. For example, based on data from Moss et al,²² Singer et al²⁹ calculated that "for the detection of proliferative retinopathy, ophthalmoscopy had a sensitivity of 0.79 and a specificity of 0.99 for 170 patients known to have proliferative retinopathy by seven-field stereoscopic retinal photography." In the study by Moss et al, proliferative retinopathy was detected in 135 patients (79%), nonproliferative retinopathy in 32 (19%), and no retinopathy in 3 (2%). However, their calculations did not assess the referral accuracy of the screening examinations. In an actual practice situation, many patients with more extensive nonproliferative disease probably would have been referred for a more definitive diagnosis, not just those judged to have proliferative disease.

Similarly, Buxton et al²⁵ measured the sensitivity of two methods of screening, dilated ophthalmoscopy by nonophthalmologists and nonmydriatic fundus photography. They had instructed their screeners to refer only if any one of seven "manifestations of sight-threatening retinopathy" was present in either eye. The authors found that the sensitivities of both methods ranged from 0.35 to 0.67, and specificities from 0.89 to 0.98. Although complete data are not presented in the article, from three to eight times as many patients were termed "abnormal, but not referred" as were "referred for retinopathy" by both screening groups. Again, in an actual practice situation, it is likely that many if not most abnormal examinations would have been referred for a more definitive examination. Therefore, screening sensitivity probably would have been higher and specificity lower. Thus, both articles overestimated the chance that serious retinopathy might be missed by the screening methods, but also overestimated specificity and underestimated the cost of screening.

Our study's conclusions regarding the relative efficacy of two screening methods for diabetic retinopathy are limited because they were done in an actual clinical setting. A major limitation was that we were not able to perform a reference-standard examination for diabetic retinopathy (ie, seven-field stereoscopic retinal photography or fluorescein angiography²⁹) on all patients. Instead, we had to rely on a "real world," practice-based standard: a full retinal examination by any of several local general ophthalmologists. Thus, we cannot be as certain

of the absolute value of our accuracy measurements. Nevertheless, we believe our findings are useful.

This study was a retrospective analysis of data gathered for the YIHC-YDESP project; therefore, referral decisions were based on clinical indications, not research reasons. Many patients in whom both the primary care ophthalmoscopic examination and the retinal photograph identified no serious diabetic disease were not referred to a local ophthalmologist for a full examination. Thus, there could have been false negatives that remained unknown to us. However, approximately 10% of all patients in whom no significant retinopathy was found during the screening examinations were referred to an ophthalmologist for refraction or for other eye problems such as cataracts, glaucoma, or decreased visual acuity. Among these patients, no significant diabetic eye disease was found.

Other limitations were that some patients had previous examinations, the results of which were available to both the YIHC physicians and photography readers. Screening of those patients did not occur *de novo*; therefore, results may have been influenced by previous examinations. However, because all screeners had the same access, it is unlikely that biases favoring one or the other screening method occurred. Also, for a few patients, the interval between referral and being examined by an ophthalmologist was long enough (occasionally up to several months) that a patient's retinal status might have spontaneously improved or worsened.

Pertinent aspects of our setting included: (1) the population screened was an unselected group of primary care NIDDM patients; (2) the primary care physicians took part in a short training session and maintained their skills by doing frequent examinations; (3) the retinal photographer was an experienced technician who took retinal photographs on a regular basis; (4) the patients' pupils were dilated during both the photography and the direct ophthalmoscopic examinations; (5) throughout most of the study, seven nonstereoscopic photographs were taken of each eye; (6) the examinations were done carefully and unhurriedly; (7) patients were referred to local board-certified general ophthalmologists; and (8) subsequent photocoagulation treatment was based on the indications that were in general use in 1988.

Although our study did not measure the absolute sensitivity and specificity of the screening methods, it indicated that under certain conditions, direct ophthalmoscopic screening by primary care physicians may be as effective as retinal photography. Our findings may be most relevant to clinicians who are concerned with the quality of, access to, and cost of screening for diabetic retinopathy. Other factors that also should be considered before choosing a screening method include: (1) the

availability of either well-trained primary care physicians or a camera and technician; (2) the skill and interest of the primary care physicians who would perform the funduscopy, the camera technician, and the ophthalmologist who would read the photographs; and (3) patient acceptance of the method.

Other circumstances may also warrant use of a particular screening method. Ophthalmologic examination by the physician allows prompt referral, avoiding the delays inherent in developing film, sending the photographs to an ophthalmologist for review, and getting the report back to the appropriate physician. In our study this process invariably took several weeks. Also, regular performance of direct ophthalmologic screening by the primary care physician increases accuracy. This advantage may be especially important for detecting disease in high-risk noncompliant patients who might not keep an appointment for retinal photography. Retinal photography, however, does provide a permanent record of the examination, which could be useful in tracking the progression of disease.

Summary

Careful screening for treatable diabetic eye disease by trained primary care physicians may be a clinically acceptable, cost-effective strategy. Similar trials should be conducted in other clinical settings, and should assess physicians' referral decisions, not clinical diagnoses. The studies should measure the absolute sensitivity, specificity, and predictive values of the referral decision for various screening methods and should estimate their costs.

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