

Cost-Effective Screening for Diabetic Retinopathy Using a Nonmydriatic Retinal Camera in a Prepaid Health-Care Setting

ANNE L. PETERS, MD
MAYER B. DAVIDSON, MD
FREDERICK H. ZIEL, MD

OBJECTIVE— To assess the efficacy of using a nonmydriatic Polaroid^R retinal camera as a method for screening diabetic patients for treatable diabetic retinopathy.

RESEARCH DESIGN AND METHODS— All 522 diabetic patients followed in a health maintenance organization–affiliated diabetes program had retinal photos taken. Compliance with the routine referral to one of two retinal specialists (the examiners) was 74%. The results from the examiners were compared with the results of the reader of the retinal photos.

RESULTS— Sensitivity was 100% and specificity was 82% for the diagnosis of serious diabetic retinopathy (preproliferative or proliferative retinopathy or macular edema) by the examiners compared with the diagnosis of any diabetic retinopathy by the reader. No patient had serious diabetic retinopathy inside or outside the photographic field that was missed because all patients with serious diabetic retinopathy showed some diabetic retinopathy within the photographic field. The reader tended to underrate the severity of the diabetic retinopathy, but when the reader diagnosed serious diabetic retinopathy, it was always present on exam.

CONCLUSIONS— The nonmydriatic retinal camera is easy to use, inexpensive, and can be used as part of a general diabetes exam, independent of a physician, in patients who should, but may not, be referred to an ophthalmologist. Any patient with abnormal findings on photos should be referred to an ophthalmologist, and any patient with findings of serious diabetic retinopathy on the photos should be referred immediately for possible laser therapy.

FROM THE DEPARTMENT OF MEDICINE, CEDARS-SINAI RESEARCH INSTITUTE, CEDARS-SINAI MEDICAL CENTER AND THE UCLA SCHOOL OF MEDICINE, LOS ANGELES; AND THE DEPARTMENT OF MEDICINE, KAISER-PERMANENTE HOSPITAL, WOODLAND HILLS, CALIFORNIA.

ADDRESS CORRESPONDENCE AND REPRINT REQUESTS TO MAYER B. DAVIDSON, MD, CEDARS-SINAI MEDICAL CENTER, DIVISION OF ENDOCRINOLOGY, ROOM B131, 8700 BEVERLY BOULEVARD, LOS ANGELES, CA 90048.

RECEIVED FOR PUBLICATION 16 JULY 1992 AND ACCEPTED IN REVISED FORM 27 APRIL 1993.

HMO, HEALTH MAINTENANCE ORGANIZATION; DR, DIABETIC RETINOPATHY; NM, NONMYDRIATIC; TYPE II DIABETES, NON-INSULIN-DEPENDENT DIABETES MELLITUS.

Treatment now exists for patients with serious DR (1), but unfortunately, most physicians do not accurately detect the presence of DR on ophthalmologic exam (2). Therefore, guidelines for yearly ophthalmologic referrals for diabetic patients have been developed (1). However, these goals are difficult to achieve because of a maldistribution of ophthalmologists, a lack of compliance with the referral to an ophthalmologist (3), and failure of referral by physicians (4). Because the eye care guidelines are not realized and screening patients for DR early in their contact with the medical care system may improve detection of treatable DR, we performed this study to test the effectiveness of an NM retinal camera as a screening tool for serious DR.

RESEARCH DESIGN AND METHODS

All 522 patients in our HMO-affiliated diabetes program from 1987–1991 had retinal photos taken with a Canon CR 4–45 NM retinal camera (Canon, Tokyo, Japan) at their initial and annual visits. The photos were taken by nurse-clinicians. All patients were routinely referred to one of two retinal specialists (the examiners). The examiners did a complete ophthalmologic exam and sent a standard exam form back to the program. Retinal photos with matching ophthalmologic reports were used if the subject went to the examiner within 6 mo of the retinal photos.

Retinal photos were taken using only physiological dark-mydriasis. The photos produce a 45° image of the retina, which includes the disc, the macula, and the temporal vascular arcades. Standard Polaroid^R Color High Speed Land Film 779 was used. The reader of the retinal photos was a diabetologist who filled out the same standard form as did the examiners.

The grading system used was as follows (5): grade 1, no DR; grade 2, minimal nonproliferative DR (microaneurysms alone); grade 3, moderate to se-

vere nonproliferative DR (microaneurysms plus hemorrhages and/or hard exudates); grade 4, preproliferative DR (venous beading and/or intraretinal microvascular abnormalities and/or cotton wool spots); grade 5, proliferative DR (neovascularization and/or vitreous hemorrhage and/or fibrous proliferans and/or laser scars). Macular edema (grade 6) was suspected if exudates were found within 1–2 disc diameters of the center of the fovea. Photos were labeled ungradable (grade 7) if any part of the retinal photo was hazy or unclear. Serious DR was defined as grades 4, 5, or 6.

The examiners examined each patient through dilated pupils using direct and indirect ophthalmoscopy as well as slit-lamp biomicroscopy with a 90-diopter Volk lens or a corneal contact lens. Although 7-field fundus photographs can identify lesions missed by ophthalmologists (6), it is not routinely available, and the accuracy of these gold standard photos may be less outside of a research setting (1). Because treatment decisions are based on the results of exams by ophthalmologists, our real world comparison seems valid.

Statistical analysis

True diagnosis of DR was based on the results of the examiners compared with the findings of the reader. Sensitivity, specificity, and predictive value were calculated based on a standard 2 × 2 contingency table (7). Ages and diabetes duration of patients with gradable and ungradable photos were compared by unpaired Student's *t* test. The effects of pupil size and presence of DR on gradability of the photos were assessed by a χ^2 analysis (7). Significance was accepted at the 0.05 level (two-tailed).

RESULTS— Of the 522 diabetic patients who had retinal photos taken, 247 were male and 431 had type II diabetes. The mean age was 50.6 yr, and duration of diabetes was 7.0 yr. Of these patients,

Table 1—Any DR by reader versus serious DR by examiners

Any DR by reader	Serious DR by examiners	
	Yes	No
Yes	31	29
No	0	129

Sensitivity, 100%; positive predictive value, 52%; specificity, 82%; negative predictive value, 100%.

436 had HMO insurance and received a free referral to the examiners; 74% of these patients complied with this referral. An additional 14 non-HMO patients were included in the study, yielding 335 patients with reports from both the reader and the examiners.

The ungradable rate was 32% (based on 1044 eye photos from 522 patients). Patients with ungradable photos were older (56.0 vs. 46.6 yr, *P* < 0.01) and more had a pupil size < 4 mm (27 vs. 7%, *P* < 0.01). Ungradability was not related to presence of DR or duration of diabetes.

Sensitivity and specificity of the photos were based on the 189 patients (378 photos) who had both eyes gradable and an examiner's report. Comparison of any DR noted by the examiner versus any DR noted by the reader yielded a sensitivity of 85% and a specificity of 93%. The lower sensitivity was attributable to the fact that the reader occasionally missed background DR that does not require treatment. The clinically important issue is to diagnose serious DR that requires treatment. The highest sensitivity for this was achieved by comparing serious DR seen by the examiner with any DR noted by the reader (sensitivity, 100%; specificity, 82%) (Table 1). If serious DR seen by the examiner was compared with serious DR noted by the reader, the sensitivity was less (74%) because of the tendency of the reader to underrate the photos. However, the positive predictive value was 100%, which means if the reader noted serious DR, it

was certain to be present on examination.

CONCLUSIONS— The NM retinal camera can be used as a screening tool to detect patients who are at risk for serious DR and need referral for an ophthalmologic exam. Used properly, the NM retinal camera has the potential to identify more patients at risk for serious DR rather than just routinely referring all patients for ophthalmologic examinations. Compliance is often poor, especially when additional costs to the patient are involved.

Using the strict criteria of the reader, 32% of the eye photos (43% of the patients) had ungradable photos. These patients were older and had a smaller pupil size. Other studies have reported that 6–22% of retinal photos taken with a similar camera are ungradable (8–10). However, poor quality photos have often been graded (9,10), but not in our study. Pharmacological mydriasis would probably lessen the ungradable rate when pupil size is < 4 mm.

All patients with serious (and therefore treatable) DR were diagnosed by the photos if all retinal photos read as having any DR were used to identify them. This approach also identified 129 patients, without DR on exam and negative photos, who would not have needed an ophthalmologic referral. A major concern (8) has been whether or not the photos would miss serious DR that lies outside of the photographic field. We had one patient with cotton wool spots only outside of the photographic field but with background DR within the field of the retinal photos. Ryder et al. (9) also found that in all cases where more serious DR was present outside the 45° field, background DR (usually marked) was present on the photos. Thus, when serious DR outside the photographic field is present, some degree of DR is usually found within the photographic field.

Our 26% noncompliance rate is

similar to the noncompliance noted in previous studies (3,11). In these studies, the knowledge of screening results suggestive of serious DR increased compliance with the ophthalmologic referral. Therefore, the NM retinal camera may enhance compliance with the ophthalmologic referral in patients found to have DR on the retinal photos.

In conclusion, an NM retinal camera can be used to screen for DR. It is effective at ruling out the presence of serious DR. Because the photos tend to underrate the severity of the DR, all patients with any disease on the photos (or with ungradable photos) should be referred to an ophthalmologist. If serious DR is noted on the photos, an emergency ophthalmologic referral should be made. Use of this screening test also has the ability to identify patients who do not need to use more costly ophthalmologic services. At the same time, it identifies patients who are more likely to have vision-threatening DR and who need incentives to enhance their compliance with the ophthalmologic referral. We feel this approach embodies the most efficient use of available health care resources.

Acknowledgments— We thank Drs. A. Sheffer and A. Shabo for performing the retinal exams; the staff of the Comprehensive Diabetes Care Service for taking the photos and tracking the data; Cesar Chavez, MD, for help in planning the study; and the physicians in the Cedars-Sinai Medical Center Independent Physicians Association.

This study was presented in abstract form at the annual meeting of the American Diabetes Association, San Antonio, Texas, 20–23 June 1992.

References

1. Screening guidelines for diabetic retinopathy: *Ann Intern Med* 116:683–85, 1992
2. Sussman EJ, Tsiaras WG, Soper KA: Diagnosis of diabetic eye disease. *JAMA* 247:3231–34, 1982
3. Sprafka JM, Fritsche TL, Baker R, Sprafka JM, Fritsche TC, Baker R, Kurth D, Whipple D: Prevalence of undiagnosed eye disease in high-risk diabetic individuals. *Arch Intern Med* 150:857–61, 1990
4. Jacques CHM, Jones RL, Houts P, Bauer LC, Dwyer KM, Lynch JC, Casale TSM: Reported practice behaviors for medical care of patients with diabetes mellitus by primary-care physicians in Pennsylvania. *Diabetes Care* 14:712–17, 1991
5. Diabetic Retinopathy Study Research Group: A modification of the Airlie House classification of diabetic retinopathy (no. 7). *Invest Ophthalmol Visual Sci* 21:210–26, 1981
6. Moss SE, Klein R, Kessler SD, Richie KA: Comparison between ophthalmoscopy and fundus photography in determining severity of diabetic retinopathy. *Ophthalmology* 92:62–67, 1985
7. McNeil BJ, Keeler E, Adelstein SJ: Primer on certain elements of medical decision making. *N Engl J Med* 293:211–15, 1975
8. Klein R, Klein BEK, Neider MW, Klein R, Klein BEK, Neider MW, Hubbard LD, Meuer SM, Brothers RJ: Diabetic retinopathy as detected using ophthalmoscopy, a nonmydriatic camera and a standard fundus camera. *Ophthalmology* 92:485–91, 1985
9. Ryder REJ, Young S, Vora JP, Ryder REJ, Young S, Vora JP, Atia JA, Owens DR, Hayes TM: Screening for diabetic retinopathy using Polaroid retinal photography through undilated pupils. *Pract Diabetes* 2:34–39, 1985
10. Williams R, Nussey S, Humphry R, Thompson G: Assessment of nonmydriatic fundus photography in detection of diabetic retinopathy. *Br Med J* 293:1140–42, 1986
11. Burns-Cox CJ, Hart JCD: Screening of diabetics for retinopathy by ophthalmic opticians. *Br Med J* 290:1052–54, 1985