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Nonmydriatic teleretinal imaging improves adherence to annual eye examinations in patients with diabetes

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Abstract—We studied whether nonmydriatic digital retinal imaging with remote interpretation (teleretinal imaging) in the ambulatory care setting affected adherence to annual dilated eye examinations among patients with diabetes. We randomly assigned 448 patients to a teleretinal imaging group or a control group. We measured the number of patients who had dilated eye examinations within 12 months of group assignment and the agreement for level of diabetic retinopathy between teleretinal imaging and the eye examinations. The teleretinal imaging group (n = 223) had significantly more dilated eye examinations than the control group (n = 225). Teleretinal imaging and eye examination results showed significant correlation and moderate agreement. Cataract and smaller pupil size were significantly associated with ungradable retinal images. Two-thirds of patients with ungradable images had other ocular findings. Patients reported high satisfaction with nonmydriatic teleretinal imaging. Nonmydriatic teleretinal imaging improves diabetic retinopathy assessment rates.

Key words: adherence, diabetes mellitus, diabetic retinopathy, digital retinal imaging, dilated eye examination, nonmydriatic teleretinal imaging, ocular pathology, rehabilitation, telemedicine, vision.

INTRODUCTION

The clinical benefit and cost-effectiveness of detection and appropriate treatment of diabetic retinopathy (DR) have been clearly demonstrated [1–2]. However, patient adherence to regular eye care is substantially less than optimal. Despite demonstrated methods of reducing the risk of vision loss from DR, up to 50 percent of patients with diabetes mellitus (DM) fail to have an annual eye examination (exam) and only 60 percent of patients who would benefit from sight-saving laser surgery are enrolled in patient care programs [3–4]. A first step in addressing this problem is to increase the number of patients receiving regular eye care.

Newly developed strategies enhance adherence to exams for DR. One such strategy uses a technology-based platform and nonmydriatic digital retinal imaging with remote image interpretation (teleretinal imaging). Such systems can obtain diagnostic-quality digital retinal images without pupil dilation and highly agree with both 35 mm retinal photography through a dilated pupil and clinical exam by a retina specialist [5–6].

Recent reports have highlighted the potential for digital retinal imaging to augment primary care treatment of patients at risk for DR [7–11]. Indeed, the operating

Abbreviations: DM = diabetes mellitus, DR = diabetic retinopathy, ETDRS = Early Treatment Diabetic Retinopathy Study, SE = standard error, VA = Department of Veterans Affairs.

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characteristics of DR detection with teleretinal imaging compare with clinic-based ophthalmoscopy [5,12–15]. A potentially important role for teleretinal imaging is to serve as a remote DR assessment and triage tool for the numerous patients with DM who are at lower risk yet require ongoing eye care. Thus, teleretinal imaging is being deployed broadly and assuming a role in the care of patients with DM based largely on observational and/or empirical data.

While teleretinal imaging technology is promising and achieving rapid acceptance, important questions have not been fully answered, including whether teleretinal imaging increases enrollment of patients with DM in eye-care programs. Since teleretinal imaging is not a confirmed routine alternative to dilated eye exam by an eye-care provider, many patients with DM still require dilated eye exams annually. Indeed, periodic comprehensive eye exams are important for assessing the stability of diabetic eye findings and screening for nondiabetic eye diseases. Thus, we tested the hypothesis that patients with DM who have teleretinal imaging added to their usual ambulatory care will have greater adherence to follow-up eye care (i.e., dilated eye exam).

METHODS

Study Participants

The study was conducted at the Department of Veterans Affairs (VA) Boston Healthcare System. The protocol was reviewed and approved by the institutional review board, and informed written consent was obtained from each participant prior to study enrollment. Participants were required to have a VA-based primary care provider and a diagnosis of DM.

Study Protocol

Participants were recruited as they came to the ambulatory care clinic for regularly scheduled appointments with their primary care providers. Appointment lists were reviewed in advance and patient records were assessed for clinical DM diagnosis (e.g., a diagnosis of DM was entered in the patient's problem list or recent clinic notes referenced care for DM). These patients were approached about possible participation in the study and 448 agreed to participate.

After providing informed consent, participants were randomized to a teleretinal imaging group or a control group. Randomization was accomplished with a random-variables generator and a series of sealed envelopes. Basic demographic and clinical data were recorded for all participants. Participants assigned to the teleretinal imaging group received the imaging procedure, and participants assigned to the control group returned to their usual care. The subset of teleretinal imaging participants (n = 60) that reported having had prior retinal photography completed a simple survey on the acceptability of the teleretinal imaging protocol.

Participant adherence to and results from a subsequent comprehensive dilated eye exam were collected by chart review. Patients were not recruited for the comprehensive dilated eye exams. Rather, these exams occurred as dictated by the participants' regular ongoing care or by new findings identified during teleretinal imaging. Participants were considered adherent if they had documented evidence of a comprehensive dilated eye exam (either VA or non-VA) during the ensuing 12 months. Information on non-VA eye exams was obtained via mail and/or telephone from patients who had no documented VA-based eye exams during the 12 months following their study enrollment date.

Teleretinal Imaging Protocol

A 2 1/2-day competency-based modular course instructed imagers in the accurate use of the nonmydriatic digital retinal imaging system. Mastery of the techniques for obtaining optimal focus, careful alignment for standardized field composition, and proper image exposure was emphasized. The imagers were trained to triage images, recognize important lesions of diabetic eye disease and related systemic disorders, and immediately alert the reader to the imminent need to read the teleretinal images.

During the participant encounter, the imager collected relevant participant demographics, medical and ocular histories, and related laboratory results, which were entered into the electronic image acquisition template. These data were uniquely linked to the retinal images through a patient study identification number. Pupil size was measured directly with a millimeter ruler.

The teleretinal imaging system that we used (Joslin Vision Network™, Joslin Diabetes Center, Boston, Massachusetts) has been described previously [5–6]. Briefly, the imager acquires single-frame video images of three 45° retinal fields using a nonmydriatic retinal camera (TRC NW-5S, Topcon America Corp, Paramus, New

Jersey) interfaced to a standard color video camera (Sony 970-MD, Sony Corp, New York, New York). For each retinal field, a stereoscopic pair of images was acquired by a manual horizontal translation of the fundus camera. An external image of each eye was also acquired for evaluation of ocular media clarity and orbital lids, lashes, and adnexa. Seven images were obtained for each eye.

After completing the imaging protocol, the imager educated the participant about the importance of optimal blood glucose and blood pressure control and demonstrated to the participant the basic anatomical structures of the ocular fundus, indicating the optic nerve, macula, and retinal blood vessels. Acting as a care coordinator, the imager later acted on the reader's report when necessary and communicated with the participant to establish an appropriate eye-exam schedule.

The digital teleretinal images and associated data were electronically transferred and reviewed by certified readers at a reading center in the Beetham Eye Institute (Joslin Diabetes Center). Stereo image viewing was achieved using liquid crystal display shuttered goggles (Stereographics, San Rafael, California). The system also allowed readers to simultaneously compare the retinal field being graded with up to three stereoscopic or nonstereoscopic Early Treatment Diabetic Retinopathy Study (ETDRS) standard retinal images [16].

The digital teleretinal images were graded stereoscopically for clinical level of DR according to a standardized protocol [5–6,16]. The presence of other ocular, retinal, and choroidal disorders was also recorded. Images were deemed ungradable for level of DR if photographic quality or other abnormality made determining the presence or degree of a lesion in at least one field impossible. In accordance with the reading protocol, if at least three disc areas of a retinal quadrant were visible in a photographic field and the retinal quadrant was lesion-free, the lesion was graded as absent rather than ungradable. Presence of a cataract was determined by observation of the pupillary red reflex and/or decreased clarity of retinal images without suspicion of other causes of media opacity. Readers filled in the clinical-findings template after reviewing each retinal image in detail, and a computer-generated algorithm calculated the level of DR using a modified ETDRS classification [16].

Statistical Analyses

All analyses compared subjects according to their status at randomization and were conducted in an intention-to-treat manner. Comparisons between groups used the chi-square analysis for categorical variables and the independent groups *t*-test for continuous variables. Relationships between variables were assessed by Spearman rank correlation and linear regression.

Adherence to a comprehensive dilated eye exam within 12 months of the randomization visit was assessed using chi-square analysis. Results of DR assessment were graded in ordinal categories. Thus, the relationship and level of agreement between results from teleretinal imaging and the follow-up comprehensive dilated eye exam were analyzed by linear correlation and the weighted kappa (κ) statistic. The weighted κ takes into account how close to agreement any failure to agree may be. Two weighting schemes exist: Cicchetti-Allison [17] and Fleiss-Cohen [18]. Since the κ values may differ quite markedly depending on the weighting factor, the Fleiss-Cohen weighting was chosen since it gives a κ that is mathematically equivalent to the intraclass correlation coefficient.

All tests were two-tailed. An α of 0.05 defined statistical significance. Statistical analysis was performed using Statistical Analysis System version 8.02 (SAS Institute, Cary, North Carolina).

RESULTS

Categorical data are presented as counts or percentages and continuous data are presented as mean ± standard error (SE) unless otherwise noted. The study participants' average age was 67 years; most were white and nearly all were male. Average duration of DM exceeded 11 years (**Table 1**). During the 12 months following the randomization visit, participants who received teleretinal imaging (n = 223) were more adherent to follow-up dilated eye exams by an eye-care professional than those who did not have imaging (n = 225) (87% vs 77%, $p < 0.01$, **Table 2**). Follow-up eye exams occurred an average 172 ± 10 days after the randomization visit for the teleretinal imaging group and 200 ± 10 days for the control group ($p = 0.08$).

Teleretinal imaging produced completely gradable images in 143 (64%) of participants. Factors significantly associated with ungradable images were the presence of a cataract and small pupil size (**Table 3**). However, among those participants with ungradable images, 56 (63%) had one or more other significant ocular finding that warranted

Table 1.
Baseline characteristics of study participants (n = 448).

Parameters	Participants
Age (yr), Mean ± SE	67 ± 1
Sex, % Male	98
Race/Ethnicity, %	
White	88
African American	10
Other	2
Smoker, %	
Yes	17
No	83
Duration of Diabetes (yr), Mean ± SE	11.6 ± 0.5
HbA1c (%), Mean ± SE	7.8 ± 0.2
Blood Pressure (mmHg), Mean ± SE	
Systolic	139 ± 1
Diastolic	75 ± 1

HbA1c = glycosylated hemoglobin, SE = standard error.

Table 2.
Adherence to eye-care follow-up within 12 months of study enrollment for nonmydriatic teleretinal imaging group (n = 223) and control group (n = 225).

Study End Point	Teleretinal Imaging	Control
Follow-Up Eye-Exam	194*	173
No Documented Follow-Up Exam	29	52

*$p < 0.01$ vs control group.

eye-care referral (i.e., cataract in 22 participants [40%], glaucoma features in 13 participants [23%], macular degeneration features in 9 participants [16%], nevus in 2 participants [4%], and emboli in 1 participant [2%]). Adherence to follow-up eye exams was not significantly different in participants with ungradable versus gradable images.

Results of the follow-up dilated eye exams were compared with teleretinal imaging in those participants with complete data for both exams (n = 140). We found a significant correlation ($r = 0.60$, $p < 0.001$) and a moderate level of agreement ($\kappa = 0.42$, $p < 0.01$) for DR diagnoses (**Table 4**). Teleretinal imaging was more likely to overidentify the presence of DR compared with the clinical eye exam, although few participants had disease beyond the mild-to-moderate nonproliferative DR level and seven standard field stereoscopic photography was not available to adjudicate discrepancies. A subset of 60 participants reported a high level of satisfaction with the teleretinal imaging exam compared with the typical retinal photography exam performed in the eye clinic. Specifically, their mean satisfaction score was 1.1 on a scale from 1 to 4, with 1 being very satisfied with teleretinal imaging.

DISCUSSION

Teleretinal imaging significantly enhanced participants' adherence to a comprehensive dilated eye exam within the 12 months subsequent to the imaging visit. DR assessments with teleretinal imaging were similar to those obtained by the subsequent comprehensive dilated eye exam, even though the two exams were not performed simultaneously. Participants reported a high degree of satisfaction with teleretinal imaging in the ambulatory care setting. Thus, teleretinal imaging proved valuable in improving access to eye care in patients with DM.

Our study was not designed to address how and why teleretinal imaging affects patients' adherence to subsequent comprehensive eye care. However, we believe that at least three possible explanations for these findings exist. First, we surmise that some of this enhanced adherence to eye care derives from identification of new cases of DR and/or nondiabetic ocular disorders. Second, the educational component of the imaging encounter, whereby the patients viewed their retinal photographs with the imager, who reinforced the need for regular eye care and discussed the role of blood pressure and glucose in the development

Table 3.
Other characteristics of patients with gradable (n = 143) and ungradable (n = 80) teleretinal images.

Parameter	Gradable	Ungradable
Cataract, n (%)	23 (16)	32 (40)*
Pupil Size (mm), Mean ± Standard Error	4.1 ± 0.1	3.2 ± 0.1†
Other Significant Ocular Findings, n (%)	54 (38)	50 (63)†
Adherence to Follow-Up Eye Examination, n (%)	130 (91)	68 (85)

*$p < 0.02$ versus gradable images.
†$p < 0.001$ versus gradable images.

Table 4.
Number of participants at each level of diabetic retinopathy as diagnosed by nonmydriatic teleretinal imaging (NTRI) versus follow-up dilated eye examination.

NTRI Diagnosis	Dilated Eye Examination Diagnosis					
	No DR	Mild–Moderate NPDR	Severe NPDR	Very Severe NPDR	PDR no HRC	HRC PDR
No DR	60	3	—	—	—	—
Mild–Moderate NPDR	35	19	—	—	—	—
Severe NPDR	3	13	—	2	—	—
Very Severe NPDR	—	1	2	—	1	1
PDR no HRC	—	—	—	—	—	—
HRC PDR	—	—	—	—	—	—

DR = diabetic retinopathy, HRC = high risk characteristics, NPDR = nonproliferative diabetic retinopathy, PDR = proliferative diabetic retinopathy.

of DR, also likely contributed to adherence to recommended follow-up. Third, the imager functioned as a care manager, contacting patients and facilitating follow-up visits when dictated by imaging results.

Adherence to guidelines for an annual eye exam in patients with DM ranges from 34 to 65 percent [3–4], suggesting an urgent need for alternative strategies for assessing level of DR. Several technologies that offer simple, low-cost, and convenient digital photographic techniques for assessing level of DR have been evaluated and compared with the ETDRS seven standard field images. Over a wide range of populations, the sensitivity and specificity of these various digital exam methods substantially agreed with the ETDRS classification for the grading of DR [5,8–15]. This substantial agreement between digital imaging and ETDRS standards appears to be consistent across a wide variety of systems, technologies, number of photographic fields obtained, image format (e.g., color vs monochromatic), and type of fundus camera used to obtain the images. Independent of the imaging system, the substantial agreement with the ETDRS classification appears to require that experienced graders interpret retinal images [12].

In the present study, a substantial number of participants had one or more ungradable images. Smaller pupil size was significantly associated with ungradable images. This finding might be interpreted as a reason to favor mydriatic exams, which have been suggested to result in fewer ungradable images than nonmydriatic exams [19]. More likely, the higher ungradable rate was related to the rigorousness of the image grading protocol, which used much higher standards than are typically applied in a clinical setting. Indeed, the frequency of ungradable images in this study does not reflect our recent experience with teleretinal imaging in which the frequency approximated 15 percent [20]. Additionally, most participants who had ungradable images also had other ocular pathologies that independently warranted follow-up eye care. This finding is consistent with our recent observations in patients with no or mild nonproliferative DR in which 59 percent had at least one nondiabetic ocular finding of a severity necessitating referral [20]. Thus, ocular disorders other than DR occur frequently in patients with DM and teleretinal imaging may facilitate their identification.

We previously confirmed a high level of agreement between management decisions based on the Joslin Vision Network™ nonmydriatic teleretinal imaging system, clinical exams, and fundus photography [5–6]. In this study, the average length of time between the teleretinal imaging visit and follow-up visit was about 6 months. Despite this time interval, the relationship between the initial teleretinal imaging exam and the follow-up eye exam was significant; teleretinal imaging actually tended to grade retinopathy higher than the follow-up eye exam. Thus, that the time interval affected the correlation of findings through progression of disease is unlikely.

While eye-care professionals diagnose and treat diabetic patients for vision-threatening conditions, primary care is typically the best site for identifying patients at risk for visual disability related to DM [7]. Teleretinal imaging in the ambulatory care setting has emerged as a potentially important clinical tool for evaluating the retina in patients with DM and assisting in adherence to practice guidelines and performance measures that recommend annual retinal evaluations for DR in most patients [21–23]. Our results confirm that nonmydriatic teleretinal imaging can potentially enhance patient adherence to comprehensive eye exams.

Widespread deployment of teleretinal imaging to assess level of DR requires that such imaging be cost-effective. The perceived value of teleretinal imaging stems from the proven value of retinal photography per se in assessing level of DR. Several studies have shown that standard fundus photography through a dilated pupil is more sensitive than a direct ophthalmoscopic exam in screening for DR [14,24–28]. However, standard fundus photography requires pupil dilation and is typically performed by trained personnel using specialized equipment to obtain ETDRS standard photographic fields [16], which reduce its cost-effectiveness as a screening tool. However, in a recent modeled cost-effectiveness analysis using decision analysis, we compared the cost-effectiveness of teleretinal imaging with the Joslin Vision Network™ versus dilated fundus exams using ophthalmoscopy in detecting proliferative DR and its consequences. We showed that nonmydriatic teleretinal imaging was the dominant strategy in all the modeled scenarios, meaning that it was less costly and more effective for detecting proliferative DR and averting cases of severe vision loss [29]. Accordingly, nonmydriatic teleretinal imaging may offer greater time-efficiency, improved adherence to eye care, and favorable cost-effectiveness in assessing level of DR.

CONCLUSIONS

In this study, we showed that nonmydriatic teleretinal imaging significantly enhanced participants' adherence to subsequent comprehensive dilated eye exams and identified DR findings similar to those obtained by an eye-care professional at a follow-up visit. Ungradable images were more frequent in participants with small pupils or cataracts, but often suggested other ocular pathologies that independently warranted referral for a comprehensive eye exam. Thus, nonmydriatic teleretinal imaging in the ambulatory care setting may improve screening rates for DR.

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