

The Clinical Utility of a Non-Mydriatic Retinal Camera in a Diabetes Clinic

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We aim to evaluate a non-mydriatic retinal camera as a safe and efficacious screening tool, for diabetic retinopathy, in diabetes centers.

Materials and Methods: 221 consecutive patients attending a Diabetes Center submitted to retinal photographs using a non-mydriatic camera. Patients were included if they had not had previous laser therapy and if they had a formal ophthalmologic consultation within 6 months of the photography. Four endocrinologists reviewed the retinal photographs and recommended an interval (urgent referral, early referral, non-referral) for ophthalmologic assessment. Endocrinologists' grades were compared against the gold standard of ophthalmologic findings. The endocrinologists were privy only to the patient's age, type and duration of diabetes mellitus.

Results: Twenty-seven cases were deemed as requiring early referral by the ophthalmologists. The endocrinologists agreed with ophthalmologist referral times in 27, 26, 23 and 27 cases respectively. Two cases requiring urgent referral according to the ophthalmologists were also judged as requiring urgent referral by all endocrinologists. A mean sensitivity of 95.4% (95% CI 88.5%-100%) was attained.

Conclusions: The use of a non-mydriatic camera to determine need for ophthalmologic referral

was found to be safe and efficacious, with no serious delays in referral noted. On average this tool can safely defer 53.5% of routine ophthalmologic referrals without any risk to the patient's eyesight.

Key Words: Diabetes Mellitus, Non-Mydriatic Retinal Camera, Screening Tool

Introduction

Diabetes mellitus (DM) is the leading cause of blindness in the Western World despite the widespread availability of effective photocoagulation treatment.¹⁻⁷ Tremendous strides have been made in the last 25 years to minimize this complication. Regular eye exams and appropriate intervention may prevent 90% of diabetes-related vision loss.⁸ Since it is less costly to detect and treat a patient with diabetic retinopathy before significant visual loss, appropriate intervention for diabetic patients is additionally an economic benefit to the health system.⁹ Improved glycemic treatment of diabetes has been proven to be effective in slowing the progression of this complication.¹⁰⁻¹² Current management recommendations require extensive dependence on ophthalmologists for the diagnosis and surveillance of this complication.^{3,14} These recommendations require most patients to see an ophthalmologist on an annual basis.¹⁵

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Consultations are time consuming for patients, involve pupillary dilation, and often require the help of a friend or family member to ensure safe travel home. These consultations also incur an expense that must be borne by the patient or health care system. In part, this may explain why ophthalmologic follow-up, according to recommended guidelines, has been noted to be sub-optimal.⁸

Our study sought to assess whether four endocrinologists each grading the same set of non-mydriatic retinal photographs could accurately identify a significant proportion of patients not requiring referral, while at the same time making few errors in identifying those who required urgent referral. The study sought to determine whether the sensitivity was $\geq 95\%$, which was deemed as the suggested criterion for employing this technique in clinical practice.

Materials and Methods

221 patients were recruited consecutively through the Diabetes Teaching and Training Center at St. Paul's Hospital, Vancouver, British Columbia over a six-month period. Patients included in the study signed an informed consent, had non-mydriatic retinal photographs taken of both eyes and visited an ophthalmologist within six months of the retinal photograph. The number of consulting ophthalmologists who were seeing these patients based on estimated referral patterns was limited to 3. Patients were immediately excluded if they had any history of laser therapy. Upon recruitment, a brief personal, diabetic and ophthalmologic history was ascertained. The study protocol was approved by St. Paul's Hospital Ethics Committee.

Retinal photographs were obtained using a Topcon non-mydriatic retinal camera. Each eye was photographed a number of times until a suitable quality or the best possible picture was obtained. The total time taken to obtain patient's history and to photograph both eyes never exceeded 10 minutes. To obtain the photographs no mydriasis was used. The

photographs produced a 45-degree image of the retina including the optic disc, the macula and its surrounding blood vessels. The photographs were captured by Image Net Lite software, and then printed using high-quality ink jet photo paper. The retinal photographs, examined by the endocrinologist, measured 10.1×7.6 cm and the circular retinal image had a radius of 3.5 cm.

Four endocrinologists (SG, SK, RM, HT) were trained by the camera operator (KJ) to read the photographs using sample photographs taken with the experimental camera. Training was brief (about 30 minutes) given the reasonable familiarity with retinal evaluation from fundoscopy possessed by the endocrinologists. Endocrinologists were then instructed to grade the photographs accordingly. The only aides, other than their own knowledge, were provided in the form of a small magnifying glass and a Progression of Diabetic Retinopathy card for reference. The latter is readily available to all endocrinologists and is provided by the American Academy of Ophthalmology. The endocrinologists were blind to the patient's identity but privy to the patient's type of diabetes, duration of disease, type of therapy and recent or, in the case of naïve patients, lack of ophthalmological findings. The photographs were interpreted and a recommended referral time was given.

Based on the interpretation of the photograph, a referral interval was suggested by the endocrinologist. These were categorized as 1- Urgent referral (less than 3 months), 2- Early referral (3 months to 1 year), and 3- No referral- (greater than one year.). Most photographs designated as poor quality were automatically designated as requiring early referral except those patients whose background (Type 1 DM, duration of DM ≤ 5 years) did not warrant such a referral.

Patients were referred to ophthalmologists with specific expertise in retinal disease and diabetes. Reports from the attending ophthalmologist were obtained based on an eye examination performed within six months of

the retinal photograph for each patient. The reports were reviewed and future consult recommendations were obtained. The patients visited an ophthalmologist as part of routine practice. The ophthalmologists were masked as to whether the patients were participating in the study. Follow-up recommendations were compared to those from the endocrinologist using the following grading system: 1- the endocrinologist and the ophthalmologist agreed on the follow-up interval, 2- the endocrinologist referred earlier than the ophthalmologist, and 3- the ophthalmologist referred earlier than the endocrinologist.

Data Analysis

The examination of the agreement between the endocrinologists' referral decision and that of the ophthalmologist included all eligible patients photographed. The rationale for including patients with unreadable photographs is that in a real clinical situation, the conservative strategy would be to give these patients an early referral, and that is how these patients were managed by the endocrinologist. The object of this analysis was to examine how often the endocrinologists made a less urgent recommendation for patients requiring referral according to the ophthalmologist and to estimate how often the endocrinologists were able to safely recommend non-referral for patients not requiring further examination according to the ophthalmologist. The sensitivities and specificities were calculated from the referral comparisons using the ophthalmologist's recommended referral interval as the gold standard.

Results

Two hundred and twenty one consecutive patients submitted to retinal photographs and a total of 442 photographs were taken of individual eyes. Thirty-nine (39) patients did not meet inclusion criteria due to either previous laser treatment (10), falling outside the allotted 6-month time frame (5) or not attending their scheduled ophthalmologic appointment (24) and were therefore excluded from the analysis. Thus cohort of 182 (47 type 1, 135 type 2) patients was utilized in the primary analysis of referral interval. Mean age was 56.0 ± 15.0 years and mean duration of diabetes was 11.6 ± 10.8 years. These patients were examined by one of three ophthalmologists: A) 95 patients, B) 52 patients and C) 35 patients. The distributions of the ratings of the 3 ophthalmologists with respect to referral were compared. There was no evidence to suggest that the ophthalmologists were using the rating scale differently (Fisher's exact $p = 0.35$).

The agreement between ophthalmologists and each of the four endocrinologists for all cases as well as sensitivity and specificity scores are summarized in Table 1. Mean sensitivity was 95.4% (95% CI 88.5%-100%). On the basis of these cases, we can say with 95% confidence that the proportion of cases for which the endocrinologist might take a less urgent recommendation is less than 11.5%. Mean specificity was 53.5% (95% CI 25.9%-80.1).

Table 1. Agreement relative to the ophthalmologists, sensitivity and specificity for each of the four endocrinologists

Endocrinologist	Urgent Referrals (U)	Early Referrals (R)	All Referrals (U & R)	Sensitivity	Non-Referrals (NR)	Specificity
1	2/2	25/25	27/27	100	20/155	12.9
2	2/2	24/25	26/27	96.3	100/155	64.5
3	2/2	21/25	23/27	85.2	120/155	77.4
4	2/2	25/25	27/27	100	92/155	59.3

Interpretation of the retinal photographs, including those automatically assigned as early referral due to poor quality, by the four endocrinologists yielded a follow-up recommendation consistent with the ophthalmologist in 47 (25.8%), 126 (69.2%), 143 (78.6%) and 119 (65.4%) cases respectively. Mean agreement was 59.8% (95% CI 36.9-82.6). A later follow-up interval was suggested by two of the endocrinologists in 1 (0.5%) and 4 (2.2%) cases respectively. The 2 cases requiring urgent referral according to the ophthalmologist were deemed as requiring urgent referral by all 4 endocrinologists (100%). The remaining cases that differed were thus designated as requiring early referral according to the endocrinologist.

Discussion

In this study we found the non-mydriatic retinal camera to be a safe tool when screening for diabetic retinopathy. Of the four endocrinologists, two assigned a later referral date relative to that assigned by the ophthalmologist in a total of 5 cases (1 and 4 each). No cases deemed urgent by the ophthalmologist were assigned as non-referral by the endocrinologists. Regardless of these few underestimations, a mean sensitivity of 95.4% was reached, assuring that the patient would almost always receive timely ophthalmological care if it were required.

In similar studies it was found that screening in a diabetes clinic setting has the potential to reduce the number of premature ophthalmological referrals and that non-mydriatic photography is a safe and efficacious screening method.¹⁷⁻¹⁸ Sensitivity for this screening method is often considered to be safe at 80%.¹⁷ In our study we sought and attained a sensitivity of 95%, which has been previously attained by Stellingwerf et al, however, in their study mydriasis was used, which is more time consuming and inconvenient for the patient.¹⁷ A previous study by Hutchison et al found that sensitivity for non-mydriatic retinal photography was lower than

when mydriasis was used;¹⁹ however, we have shown that non-mydriatic fundus photography can be as sensitive as fundus photography carried out using mydriasis. The endocrinologists were able to assess the need and timely referral for an ophthalmologic consultation.

The number of cases judged by each of the 4 endocrinologists as having at least one poor quality photograph were 33 (18.1%), 37 (20.3%), 35 (19.2%) and 34 (18.7%) resulting in exclusion of these patients from secondary analysis. Mean exclusion percentage was 19.1% (95% CI 18.2%-20.0%). This figure approximates the rate of ungradable photographs as determined by other studies, which had unassessable photograph rates of 17.3%, 17.5% and 18%.²⁰⁻²² Our figure is considerably lower than the percentage of poor quality photographs as determined by Peters et al (32%) in a similar study.²³ In our study poor quality photographs were often obtained from patients who were elderly, had small pupils, had media opacities (such as cataracts) or a combination thereof, which is consistent with the findings of other studies involving non-mydriatic retinal cameras.^{21,22,24} Klein et al found there to be a disagreement, in terms of grading, of 17.5% between photos taken through undilated pupils and the standard of 30 degree standard fundus photography due in most part to poor quality photographs.²⁵

In this study the reader was privy to the age, sex, diabetes history and recent ophthalmologic findings of each patient. These demographics allow the study to more accurately simulate the clinical conditions during which patients will be examined by the endocrinologist and subsequently photographed since the endocrinologist will have access to each patient's chart during examination. The demographic information greatly improved the proportion of safe deferrals compared to our previous study, which involved only 1 endocrinologist grading the photographs, from 21.4% to a mean of 53.5%.²⁶ In addi-

tion, including four endocrinologists as readers improves the validity of the study since the chance of simply having one extraordinary photograph reader is eliminated.

In the 2 cases requiring urgent referral as deemed by the ophthalmologist, each endocrinologist recommended urgent referral in both cases. For those cases requiring early referral the endocrinologists were very accurate in terms of agreement resulting in a mean sensitivity of 95.4%, leaving only 4.6% of the ophthalmologist's early-referred cases as non-referrals. These referral times are safe and ensure that the likelihood of missing a case requiring early referral is small. The small number of patients requiring urgent referral can be explained by our strict exclusion criteria; since patients who have had previous laser therapy were excluded this left only patients without serious past retinopathy. This is justifiable as we feel such patients must all have ongoing ophthalmological assessments, and thus are not candidates for any screening tools, such as our camera.

In our study the comfort of the patients during the photography session was not directly assessed; however, the retinal photographs were usually completed within five minutes, in conjunction with a scheduled visit at the Diabetes Center. Ophthalmologic visits with

formal pupillary dilation take a minimum of one hour and often longer depending on the ophthalmologist. Therefore we feel another benefit of non-mydratic retinal photography will be greater patient acceptability, satisfaction and compliance. It also serves as an educational tool, reminding patients of the importance of eye care as a part of complete diabetes care.

Based on this study, we can conclude that this method of retinal screening can be safely used to determine the need for ophthalmologic referral. The technology is easily utilized in the clinic setting as an adjunct to usual patient care.

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