Mass community screening for diabetic retinopathy using a nonmydriatic camera with telemedicine

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ABSTRACT • RÉSUMÉ

Background: Diabetic retinopathy is a leading cause of blindness. Studies have shown the value of screening and early, timely treatment. Our aim was to measure the effectiveness and degree of acceptance of community screening for diabetic retinopathy using telemedicine.

Methods: In this prospective, population-based cross-sectional study, diabetics recruited through a regional multimedia campaign were surveyed and screened for retinopathy using a nonmydriatic camera and evaluated through telemedical imaging.

Results: Of the 291 diabetics recruited over a 3-week period (37% by the regional diabetes association and 30% by the media), 49.4% reported having their most recent eye examination within 1 year, 30.7% between 1 to 2 years, 9.7% over 2 years, and 10.1% had never had an exam. 98.6% found our screening method acceptable, with 95.1% wanting to return for their next screening and 91.2% stating it would increase their compliance to annual screening.

Interpretation: Telemedicine provided a reliable and highly acceptable method for diabetic retinopathy screening. It can attract a significant number of people with diabetes and potentially recruit patients who would otherwise be missed by the current methods of vision screening.

Contexte : La rétinopathie diabétique est une des causes principales de cécité. L'importance du dépistage de la maladie et de son traitement précoce et au moment approprié ont été bien démontrés. Notre objectif était de mesurer dans une communauté, l'efficience et le niveau d'acceptation du dépistage de masse de la rétinopathie diabétique par télé médecine.

Méthodes : À l'occasion de cette étude populationnelle prospective et transversale, un programme de communication régional et multimédia a permis le recrutement des personnes diabétiques chez qui un dépistage de la rétinopathie diabétique par caméra non mydriatique a été fait dans un cadre de télé médecine.

Résultats : Des 291 diabétiques recrutés en trois semaines (37 % par l'association régionale de diabète et 30 % par les médias), 49,4 % avaient subi leur dernier examen oculaire depuis un an, 30,7 % depuis 1 an à 2 ans, 9,7 % depuis plus de 2

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ans et 10,1 % n'en avaient jamais subi. 98,6 % des participants ont évalué cette approche acceptable dont 95,1 % souhaitant leur prochain examen de dépistage fait de la même façon et 91,2 % prédisant ainsi une meilleure compliance à leur dépistage annuel.

Interprétation : Cette stratégie de dépistage par télé médecine a constitué une méthode fiable et très acceptable pour le dépistage de la rétinopathie diabétique. Elle permet le recrutement d'un nombre significatif de diabétiques et offre le potentiel de récupérer des patients qui passeraient autrement outre des recommandations actuelles des soins oculaires pour le diabète.

Diabetes mellitus affects more than 1.3 million Canadians, and 60 000 new cases are diagnosed each year.[1] Among patients diagnosed with diabetes for over 20 years, 99% with type 1 and 60% with type 2 of the disease will have some degree of retinopathy. In the western world, diabetic retinopathy (DR) is the leading cause of blindness in people 20 to 65 years of age. Major studies have shown that severe ocular complications can be avoided or lessened in many patients through early diagnosis by regular eye examination. Despite established comprehensive guidelines for systematic screening for diabetic retinopathy,[2] adoption of yearly screening examination in the clinical setting has been poorly followed.[3–5] Factors affecting level of adherence to recommended guidelines include advanced patient age, type of diabetes, duration of disease, and the need for pupil dilation. Limited access to ophthalmologists appears to be one of the most significant reasons for poor adherence, particularly in remote areas.[3,6–8] Hence, the application of telemedicine to deliver health care to remote areas can be an attractive alternative to overcome the limitation in accessibility to specialists.

The wide variation in adherence rates found in various studies, and the apparent lack of improvement despite ongoing efforts at educating both patients and physicians, indicate the need to examine and develop new solutions in the current health care system. There is increasing interest in the use of telemedicine as a means of health care delivery.[9–12] Wise use of this tool for screening for DR is particularly interesting in a context where accessibility is restricted.

This study is part of a major project studying the effectiveness of retinopathy screening using a nonmydriatic fundus camera in a community-based population in Quebec. This project aims to investigate methods of patient sensitization to diabetes eye care and patient patterns of nonadherence to eye examination scheduling. It also studies the effectiveness of community screening for diabetic retinopathy using telemedicine and measures patient perception and acceptance of this mode of health care delivery.

Methods

Study recruitment was open to all residents of Varennes, Que., with a known diagnosis of diabetes. To identify potential participants, a community-wide multimedia communication campaign was undertaken for 2 weeks before enrollment. The media campaign consisted of an on-site press conference on diabetes, its related visual complications, and the importance of regular eye examinations, as well as news coverage in 10 regional and local newspapers. In addition, regional healthcare professionals involved in the management of diabetes, including family physicians, endocrinologists, pharmacists, and optometrists, were contacted by mail, invited to the press conference and, on 2 occasions a week apart, visited personally by the recruitment team, which was composed of a general practitioner and a postgraduate student in communication. Five thousand posters and brochures were distributed to strategic locations, including pharmacies, local health centers, and medical and optometric clinics, to facilitate recruitment for the study. A letter was sent by the Quebec Optometrist Association to regional optometrists to encourage their participation in the project. Local and provincial diabetes associations and patient support groups also collaborated for recruitment by contacting all members residing in the area by mail and by telephone. Finally, the project was advertised in the most recent issue of the monthly journal of the Quebec Diabetic Association.

During the 3-week recruitment period, diabetic patients who enrolled in the study were instructed to

call a toll-free number to make an appointment for the photographic screening examination. At the same time, visits within the next 2 months for a complete ophthalmologic examination with pupil dilation were scheduled for the participants with either of the 2 local ophthalmologists. All requests for further information on the project or on general aspects of diabetic retinopathy were forwarded to a trained information agent to be addressed immediately.

Telemedicine screening

Fundus imaging of both eyes of each participant was performed, after informed consent had been obtained, at the CLSC des Seigneuries (Regional Health Centre) between April 3 and April 28, 2001, using a nonmydriatic retinal camera (model TRC-NW5S, Topcon Medical Systems, Inc., Paramus, N.J.). Four nondilated fundus photographs of each eye were taken, centered on the disc, the macula, the temporal superior area, and the temporal area of the macula. The images were initially saved on the local hard drive in tagged image file (tif) format and transmitted at the end of each day to the hospital server, with lossless compression (WINZIP 1, 6:1) through the FTP transfer protocol on the Quebec socio-sanitary transmission network (RTSS) with a 256 kbit/s Internet connection. No problem was encountered or reported during the transmission of the images. The screening modalities, including image capture, transmission, and analysis, were identical to that of previously published studies[13,14] where agreement, sensitivity, specificity, false positives, and false negatives were measured against the 7 standard stereoscopic 30°, 35 mm photographs of the Early Treatment Diabetic Retinopathy Study Research Group (ETDRS).[15]

Within the next several days, 2 ophthalmologists located at the hospital reading center performed image quality analysis to define image quality using the following criteria: grade 1, excellent definition; grade 2, good definition of most details; grade 3, definition limited but permitting confident assessment; grade 4, insufficient definition for confident assessment; and grade 5, only gross or no details visible. Quality grades 1, 2, and 3 were considered to be of sufficient quality for interpretation. Classification of the severity level of DR of the imaged fundi was performed using the modified Welsh classification,[16] as this was believed to be more reproducible for clinical grading performing the dilated fundus examination of each eye.[13] The 2 regional ophthalmologists who performed eye examinations directly with the study subjects adopted identical DR severity disease grading with the same classification model. Thus we defined very mild DR as grade 20 on the ETDRS scale, and mild DR as grade 35.[15] These 2 ophthalmologists also implemented patient care and follow-up.

Three questionnaires were administered to all participants: (1) at the time of enrollment to profile each participant, (2) after the imaging session to survey the acceptance and satisfaction with the photographic telemedical screening process, and (3) after the examination with the ophthalmologist to evaluate the difference between the traditional screening method and the new telemedical technology as perceived by the participants.

Table 1—Sociodemographic data of participants in telemedicine community screening program for diabetic retinopathy (*n* = 291)

Male, (no.)	59% (172)
Median age, years	59
Age range, years	17–87
Type 2 diabetes, (no.)	85.9% (250)
Mean known duration of diabetes, years	9.6
Insulin therapy, (no.)	27.4% (80)
Participants aware of diabetes' threat to vision, (no.)	95% (276)
Participants acquainted with a person visually handicapped as a result of diabetes, (no.)	47.1% (137)

RESULTS

Sociodemographic data

Two hundred ninety-six (296) people with diabetes responded to the recruitment campaign, and 291 (98.3%) attended their appointment for the screening examination. There were slightly more male subjects then female, and the median age was 59 (range 17–87) years. Demographic data for the cohort are shown in Table 1. Two hundred and fifty (85.9%) of the participants were diagnosed with type 2 diabetes. The mean duration of diabetes was 9.6 years. Approximately one fourth of the cohort were on

Table 2—Source of recruitment from communication campaign (*n* = 291)

	% of participants (no.)
Local or regional diabetes associations	37 (108)
Media	30 (87)
Medical clinics	15 (44)
Word of mouth	9 (26)
Posters in pharmacies	8 (23)
Optometrists	0 (0)

Table 3—Compliance with guidelines for yearly screening examination for diabetic retinopathy

Time since last eye examination	% of participants (*n* = 267)
Less than 1 year	49.4
1 to 2 years	30.7
More than 2 years	9.7
Never	10.1

insulin therapy. When questioned about diabetes-related visual problems, almost all were aware of the potential for vision complications associated with diabetes and the risk of a severe visual handicap. Moreover, almost half admitted having an acquaintance with a visual handicap related to diabetes. Some degree of diabetic retinopathy was found through image grading in 22% of participants.

Recruitment source

Of the 291 recruited subjects, the largest group (108) responded to the project as a result of their participation in local or regional diabetes associations. A third enrolled as a result of advertisements in regional newspapers, 15% originated from medical clinics, and the remainder were divided between those hearing about the project from friends and relatives, and those seeing posters related to the project in pharmacies. There were no referrals from optometrists. Details of the recruitment sources are shown in Table 2.

Table 4—Factors of noncompliance with yearly screening examination

	% of participants (no.)
Reason for last eye exam more than 2 years ago (*n* = 54)	
Negligence	28.3 (15)
Difficulty in obtaining an appointment	11.2 (6)
Examination not important	4 (2)
Examination unpleasant	2 (1)
Noncompliant due to negligence (*n* = 15)	
Type 2 diabetes	93 (14)
Aware of diabetes threat to vision	100 (15)
Acquainted with a person having a visual handicap from diabetes	47 (7)

Evaluation of compliance to guidelines

Adherence to screening guidelines was evaluated by the third questionnaire received from 267 patients (Table 3). Approximately half claimed to have had an eye examination within the last 12 months. One third had their last check-up between 1 and 2 years before the study, and the remaining patients were split almost evenly between having had their last examination more than 2 years before, or having never had an eye examination for diabetes.

Of the 54 patients who had not been screened for over 2 years, 15 stated negligence as the main reason (Table 4). Other reasons for noncompliance with the guidelines included difficulty in getting an appointment (6) and unpleasantness of the examination (1). As well, 2 did not think that examination for diabetic retinopathy was important. Of the 15 who had not had eye screening for over 2 years out of neglect, analysis revealed that 14 suffered from type 2 diabetes. All were aware that diabetes represents a threat to vision and 7 had a personal acquaintance living with a visual handicap related to diabetes. When questioned about their next planned appointment, 2 did not have any scheduled examination or plan to have a scheduled examination in the foreseeable future. Further analysis revealed the presence of noncompliance in all socioeconomic classes, from annual income below $25 000 to annual income above $100 000.

Table 5—Eye care by primary caregiver

	% of participants (no.)	
	Ophthalmologist	Optometrist
Primary eye care provider	79.5 (182/229)	17.9 (41/229)
Pupil dilation during last examination	87.9 (160/182)	42.5 (17/40)
Last eye exam more than 2 years ago	9 (16/177)	5.4 (2/37)
At least very mild* diabetic retinopathy	17 (30/177)	13.4 (5/37)

*Very mild diabetic retinopathy = ETDRS grade 20 classification, Early Treatment Diabetic Retinopathy Study Research Group.[15]

Table 6—Quality of fundus photographs at screening examination, and diagnoses

	% of participants (no.)
Images of sufficient quality for interpretation (*n* = 291)	81.7 (238)
Imaging grading (*n* = 238)	
At least very mild DR*	22.0 (52)
At least mild DR*	9.5 (23)
Images of insufficient quality for interpretation (*n* = 291)	18.3 (53)
Ophthalmologist grading (*n* = 53)	
At least very mild DR*	18.0 (9)
At least mild DR*	11.0 (6)

Note: DR, diabetic retinopathy.
*Early Treatment Diabetic Retinopathy Study Research Group,[15] very mild DR = ETDRS grade 20, mild DR = ETDRS grade 35.

Table 7—Patient acceptance of eye examination for diabetic retinopathy through telemedical imaging (*n* = 291)

	% of participants (no.)
Screening through imaging was very acceptable	90.8 (264)
Screening through imaging was acceptable	7.8 (23)
Satisfied with the screening experience	98.6 (287)
Would prefer it over traditional exam for next screening	95.1 (277)
Express future compliance with this screening strategy	91.2 (265)
Preference over a standard examination by an ophthalmologist	82 (239)

Caregiver involvement

The distribution of professionals involved in primary eye care is listed in Table 5. When asked what healthcare professional performed their last examination, almost 80% (182/229) of participants recalled being seen by an ophthalmologist and almost 88% of these patients recalled having pupil dilation. In contrast, less than half of those who had been examined by an optometrist recalled having had their pupils dilated. Six of the 229 patients stated that their family physicians performed the last eye examination, with 3 out of 6 recalling pupil dilation.

Screening

As shown in Table 6, the captured fundus photographs of 238 patients (81.7%) taken at the screening examination were graded to be of sufficient quality for interpretation. Of these participants, 22% were found to have some diabetic retinopathy and 9.5% to have greater than level 35 ETDRS scale DR.[14] Among those 53 patients whose images were judged to be of insufficient quality for interpretation, clinical examination by the regional ophthalmologists revealed very mild DR in 9 cases (18%) and greater than mild DR in 6 cases (11%).

Acceptability of the technology

As shown in Table 7, most participants found it acceptable (90.8% very acceptable, 7.8% acceptable) to have a screening eye examination performed by a camera coupled to a telemedicine system in the absence of an ophthalmologist, and to be referred to an ophthalmologist for a complete examination only if disease were detected by the screening. Almost all (287, or 99%) were satisfied with the information and services provided by the screening team and with

their experience with the photographic examination with the nonmydriatic camera. Also, 277 participants (95%) indicated they would like their next screening examination performed by a similar telemedicine system rather than by an ophthalmologist, with referral to an ophthalmologist only when necessary. Most importantly, 265 (91%) said they would be more compliant with receiving regular eye screening with imaging through telemedicine.

More than 4 out of 5 participants (82%) stated a preference for the photographic examination over standard eye examination by an ophthalmologist. The reasons given were absence of eye drops, absence of pupil dilation following drops, and rapidity of the photographic examination, as well as less annoyance and greater ease of accessibility.

On the other hand, 18% felt that a standard eye examination with an ophthalmologist was irreplaceable because they believed in the importance of personal interaction with an eye care professional and enjoyed having immediate results given by their doctor. A small number (9, or 3.2 %) admitted they did not trust the technology and questioned the validity of the camera.

Interpretation

In addition to providing accurate diagnosis and early treatment, the challenge in establishing an effective screening program for DR lies in reaching as many at-risk people as possible, using simple, available, and cost-effective modalities.[17] This study aimed to determine the acceptability of a telemedicine screening modality for DR in a community setting and to measure its potential public health impact. Additionally, it measured the efficiency of different recruitment strategies in reaching the target population.

In our study, diabetic retinopathy was observed in 22% of the patients whose fundus photographs from the telemedical screening exam were sufficient quality to be interpreted. This is in accordance with the expected 20% disease rate found in a general diabetic population[18,19] and reflects an unbiased population selection in our study.

According to the Canadian guidelines, diabetics should undergo an eye examination annually. Results from our study indicated that 50.6% of patients had not had an examination in the previous 12 months. Similar rates of noncompliance have been observed in other studies.[8,20–25]

The sizable number of participants enrolled within a short 3-week recruitment period reflects the interest of diabetic patients in seeking visual care when reminded and when given the opportunity. Other investigators have observed similar findings.[21,26,27] In our study, referral by the regional diabetic association appeared to be the most efficient way for subject recruitment. This emphasizes the benefits of working closely with community groups associated with diabetes for the purpose of implementing health programs. Our study showed that close collaboration with concerned diabetes community groups, in combination with information provided to the local media and to regional medical clinics, was the most successful approach to recruit the diabetic population in a screening program for DR. The coordinated approach of these 3 modalities recruited 82% of our participants, which corroborates results from other studies.[28,29]

Optometrists did not result in any recruitment, although optometrists knew 17% of the recruited patients and the optometric community had indicated willingness to collaborate with recruitment for this study. It is possible that this group of eye care providers may not have seen any diabetic individuals during these 3 weeks of recruitment.

This communication campaign and novel approach to screening was able to recuperate those patients (19.8%) in our study who had neglected their eye condition for over 2 years and had been lost to screening within the traditional health care system. Most (93%) of the patients who were noncompliant due to negligence were type 2 diabetics, reflecting the known predominance of type 2 diabetes (90%), and perhaps the lesser incidence of insulin treatment in this group of patients, which is a known factor in nonadherence to screening guidelines.[3]

Measures of the main factors associated with nonadherence to screening guidelines in the noncompliant group of patients in our study provides valuable information about better ways to reach these people in a public health program. The known threat of disease does not appear to be a sufficiently motivating factor to command screening in this group, since a considerable proportion (28.3%) did not comply because of neglect even though all were fully aware that it could lead to a visual handicap and half had a personal acquaintance living with a visual handicap related to diabetes. Several factors may account for the success of our study in bringing forward some individuals of that group for screening. They may have

perceived the screening process as "de-medicalized" or outside the normal medical sphere. They may also have been relieved of the perceived threat of medical screening, such as fear of being told of the presence of a disease by a doctor. They may have been convinced to comply because telemedicine increases the ease of access to screening, and because our communication program may have reinforced their awareness of DR.

As found by Schoenfeld et al,[3] we also found that the group of noncompliant patients was represented equally at all socioeconomic levels. This raises the possibility that universal issues found in all socioeconomic groups, such as psychological concerns, may be more important obstacles to compliance to screening than previously thought, as suggested by Sinzato & al,[30] and that the influence of income may play a less significant role.

The rate of dilated eye examinations recollected by the participants was surprisingly low. Patients reported only 88% of ophthalmologists and 42.5% of optometrists had performed pupil dilation during previous examinations. Although this information should be interpreted with caution because it is derived from patient recollection, it does underline the importance and need of continued education on the guidelines for performance of clinical DR examination. Our results were also in accordance with the study of Schoenfeld et al,[3] which identified nonmedical eye care providers as the most important factor predicting deviation from recommended examination procedures for DR. However, from the answers to our questionnaires, we noted that 9% of patients last examined by an ophthalmologist had not had their eyes examined for over 2 years, whereas this was true of only 5.4% of patients last examined by an optometrist. Although this information, derived from questionnaires, must be interpreted with caution, it may suggest that a regular patient-recall procedure for clients, as is usually done in optometric practices, may favour compliance to regular eye examination, and this has been measured by other authors.[26,27]

In the present study, including those patients referred because of insufficient quality of the images, a chosen screening threshold of very mild DR (≥ ETDRS grade 20) or greater than mild DR (> ETDRS grade 35) would lead to referral to an ophthalmologist for examination of 36.1% and 26.1% of the participants, respectively, underlining the important economic potential of this approach.

Insufficient quality of the captured images for interpretation was found in 18.3% of the patients, which in a real-life situation would have led to ophthalmology referral for appropriate examination. The regional ophthalmologists who performed the clinical examinations of these patients found very mild DR (≥ ETDRS grade 20) in 18% of them and greater than mild DR (> ETDRS grade 35) in 11%.

This telemedicine DR screening strategy has the merit of allowing effective usage of specialists. In this program, patients who have no pathology picked up by the initial screening will not require special care with a specialist and can continue to be monitored by the annual telemedical screening program. Ophthalmology care, which is generally limited in remote areas, can thus be directed to patients with pathology who require active management. In this project, if we had used a screening threshold for referral of very mild or mild DR, it would have resulted in referral for only 36.1% or 26.1%, respectively, of all patients screened (including those referred for insufficient quality of images), rather than the 100% that would otherwise need to be examined to comply with screening recommendations. The low false-negative rate (1.0%) and low false-positive rate (3.1%) that were measured in a previous study,[13] using an identical screening strategy, provide confidence in the accuracy of the results obtainable from telemedical screening.

Among the reasons patients listed for not following through on annual screening were inaccessibility and difficulty in getting an appointment with a care provider, as stated by 14% of the noncompliant group. In the context of limited medical resources and economic restrictions on health care, telemedicine and new imaging technologies may provide a cost-effective and efficient alternative screening strategy for DR.

Screening for DR using telemedicine and a nonmydriatic camera appears to be highly acceptable and satisfactory to patients. More compelling are the results concerning the intention of 91% to be more compliant to an eye-screening regimen with this technology, although it remains to be verified if this intention will translate into improved compliance and sustained behavioural changes in the future in this populations.[4,5] The participants' visualization of their own fundus images appeared to increase their awareness and comprehension of the disease. The participants also appreciated the absence of the need for pupil dilation, which may increase their compliance to regular screening.[6]

This project measured this population's high degree of readiness to adopt a new technology for DR screening through telemedicine with a nonmydriatic camera. It also demonstrated the capacity of this technology to recover people with diabetes who had been lost to screening within the traditional health system. It attracted a significant number of diabetic individuals who found the process highly acceptable. It confirms that such a screening strategy through telemedicine with fundus imaging is simple, efficient, and decreases obstacles to screening. It emphasizes the importance when implementing health programs of working closely with community groups associated with diabetes and with the media to reach the target population. More studies are needed to fully evaluate the conditions of implementation of telemedicine for DR screening, such as patient compliance, site of screening, and health and economic outcomes.

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