

Diabetic Retinopathy Education and Screening at the Community Pharmacy in Puerto Rico

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Objective: Diabetic retinopathy (DR), the most common diabetes-related eye disorder, is associated with poor glucose control and is the most frequent cause of adult-onset blindness. The purpose of this study was to demonstrate that pharmacists can play an effective role in identifying individuals at risk for developing DR, educating them about DR, facilitating access to diagnostic eye exams, and referring patients diagnosed with vision problems or other conditions for treatment and continuing care.

Methods: This two-phase project was conducted at two independent community pharmacies in Puerto Rico. Phase I consisted of open educational sessions at each pharmacy to create citizen awareness of DR, while on the phase II screening days, an ophthalmologist conducted eye examinations of pharmacy customers in order to diagnose possible vision problems. For those participants diagnosed with vision problems, the results of their exams were sent to their preferred ophthalmologist.

Results: Seventy-two patients who participated in phase I at the two community pharmacies were selected to receive ophthalmologist exams in phase II. The mean age of these participants was 58 years, and 76% were female. Sixteen of the patients (22%) evaluated in phase II were diagnosed with diabetic retinopathy and were referred to their preferred ophthalmologist or primary care physician for follow-up evaluations and treatment. Fourteen patients (19%) were diagnosed with glaucoma. Four of these glaucoma patients were among the 16 patients who were diagnosed with DR.

Conclusion: The community pharmacy is an excellent venue in Puerto Rico where citizens can be educated and informed about the problems of DR and examined medically to identify those with undiagnosed diabetic retinopathy or, if such is the case, other vision problems. Once diagnosed, these patients can be promptly referred to their preferred ophthalmologists for treatment and follow-up care. [*P R Health Sci J* 2011;30:139-144]

Key words: Diabetic Retinopathy, Community Pharmacy, Diabetes Education

Diabetic retinopathy (DR), the most common diabetes-related eye disorder, is caused by changes in retinal blood vessels resulting from poor, long-term glucose control. The retina is the light-sensitive tissue at the rear of the eye, and retinal damage can result in vision loss and/or blindness. In some individuals with DR, blood vessels may swell and leak fluid, while in others, abnormal new blood vessels (neovascularization) can grow on the surface of the retina. The DR condition is classified in four stages, and proliferative retinopathy is the last and most severe of these four stages. Unless diagnosed and treated promptly at this late stage, DR can result in severe loss of vision or even in blindness.

According to the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), 24 million people are estimated to have diabetes in the United States in 2007, representing approximately 7.8% of the US population (1, 2). Among an estimated 10.2 million adults 40 years or older known to have diabetes in 2007, the crude prevalence rates for retinopathy and vision-threatening DR among this

population with diabetes were estimated to be about 40.3% and 8.2%, respectively (3). Future projections suggest that DR will increase as a public health problem as the population of the United States ages and as the age-specific prevalence of diabetes increases (as it is predicted to do over time) (3).

In Puerto Rico, the proportion of adults who have been diagnosed with diabetes increased from 8.5% in 2000 to 12.6% in 2004 (4). Other studies have suggested that the prevalence of diabetes in 2004 was even higher, being as much as 14% (4). In 2008, the Behavioral Risk Factor Surveillance System estimated

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The authors have no financial interests to disclose.

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that the prevalence of diabetes in Puerto Rico remained at about 12.5% of the population older than 18 years of age (5). At 12.5%, the prevalence of diabetes among adults is higher in Puerto Rico than it is in any other state or territory in the United States.

DR is the most frequent cause of blindness in adults (20 to 74 years old) (6), and it very severely affects the quality of life of these patients. Vision loss from DR is preventable if the disease is diagnosed and treated early. Studies have demonstrated that the early detection of DR results in significantly lower costs in terms of healthcare, not only because such detection allows for early treatment but also because it prevents disease progression and related complications (7, 8). In the Diabetes Control and Complications Trial (DCCT) (7), all participants diagnosed with type 1 DM were treated with intensive insulin therapy and monitored for progression to DR. For participants with no eye damage, the risk for developing retinopathy was reduced by 76 percent. For participants with some eye damage at the beginning of the study, intensive diabetes management was shown to slow the progression of the disease by 54 percent (7).

The United Kingdom Prospective Diabetes Study (UKPDS) (8) also demonstrated that the development or progression of retinopathy can be diminished in patients diagnosed with type 2 DM by lowering blood glucose levels with intensive therapy. In this study, median levels of glycosylated hemoglobin A1c (HbA1c) were reduced to 7.0% (9).

The population afflicted with diabetes in Puerto Rico is expected to continue increasing. It is therefore extremely important to develop new strategies to prevent such increases in the number of individuals in Puerto Rico with undiagnosed and untreated DR. In Puerto Rico, traditional medicine has been underdiagnosing diabetes, and as a result, glycemic control is poor in many island residents (5). Opportunities to meet the challenges of diabetes in Puerto Rico lie in the four elemental points: primary prevention, screening and early diagnosis, access to care and education, and quality of care (8).

The lack of DR awareness is a problem and is of concern even in terms of people recently diagnosed with diabetes. In a recent Indian study, only 15% of persons newly diagnosed with diabetes at screening camps and referred for further assessment followed recommendations for diabetic retinopathy screening. This result demonstrates that there is great need to improve education and enhance awareness among patients with diabetes about the microvascular complications related to poor glucose control (10).

Many barriers still need to be overcome in the challenge to reduce diabetes-related vision disorders. A number of underutilized assets in this fight against such chronic healthcare problems are non-physician healthcare professionals, such as nurses and pharmacists, and non-healthcare professionals, such as faith and community leaders and employers. A new strategy is to involve them in efforts to improve health awareness, in the implementation of programs of prevention, screening,

and the early diagnosis of chronic diseases or conditions, and in the development of new approaches to improve access to quality healthcare. Implementing such a strategy could help to decrease the great healthcare disparities that exist between socioeconomic classes across different regions of the island and to gain the cooperation of families in the screening and treatment of infants and children (11).

Pharmacists, in particular, can play an important role in those educational outreach efforts that focus on the prevention and early detection of DR and other conditions. These healthcare professionals could develop and coordinate programs in their communities to provide education about healthcare problems such as DR and about the benefits of prevention and early diagnosis, facilitate patient access to examinations, and, in general, contribute to improving the health and quality of life for all citizens of Puerto Rico. Community pharmacies have a great potential to serve in the benefit of their clients in this regard, because they have a large customer base and because it would be easy for such pharmacies to collaborate with other local healthcare providers on the coordination of educational and screening services.

The primary objectives of this study were 1) to highlight the role of the pharmacist as a health care professional who provides education and prevention and detection services for diabetic retinopathy (DR) and other vision complications associated with chronic diabetes; 2) to identify individuals within the service population who had chronic diabetes and who were at risk for developing DR and to enhance their awareness of both the importance of glucose control to the prevention of DR and the necessity of an annual eye exam to diagnose the condition; and 3) to conduct free ophthalmological examinations on eligible study participants to diagnose DR, referring those with diagnosed disease to the ophthalmological specialist of their choice for treatment and continuing care in order to prevent or minimize DR-related vision loss.

Methods

The protocol for this study was approved by the Office for the Protection of Human Participants in Research of the University of Puerto Rico (UPR) Medical Sciences Campus. The study was conducted onsite at each of two community pharmacies in Puerto Rico: Farmacia Del Pueblo in Barranquitas and Farmacia San José in Lares. Each pharmacy signed an agreement to collaborate with UPR on conducting the study, which consisted of a phase I DR open educational session and a phase II DR screening day.

Phase I - DR Open Educational Sessions

Phase I open educational sessions (followed by Phase II screening-day sessions) were conducted in 2003 and 2004 at two separate community pharmacies in the Puerto Rican towns of Lares and Barranquitas. The two community pharmacies were

responsible for promoting the open educational sessions and for coordinating all session activities. The educational sessions were targeted at the residents living in the vicinity of each of the two community pharmacies who had already been diagnosed with type 1 or type 2 diabetes mellitus. The sessions were designed to provide targeted persons with information that would enhance their awareness of the importance of glucose control in the prevention of diabetes-related complications that could harm their vision, and to emphasize the importance of having an annual dilated-eye examination that could diagnose DR early enough such that prompt treatment could prevent vision loss or blindness. Primary care physicians in the areas surrounding the two community pharmacies were encouraged to recommend that their patients both attend the educational sessions and later seek out annual eye exams for the early identification of retinal changes that could be harmful.

The open educational sessions were conducted by investigators, who were working under the supervision of Dr. Francisco J. Jiménez. A portion of the space in each pharmacy was arranged to accommodate the audience for the educational sessions. The educational program included information about risk factors for vision problems, prevention, treatment, the importance of diabetes control (e.g., controlling levels of HbA1c < 7%), other health conditions such as hypertension and dyslipidemia, and the importance of an annual dilated-eye examination. Information about DR (in Spanish) was acquired from the National Eye Institute (NEI) of the National Institutes of Health (NIH) and from “Sociedad Puertorriqueña para el Cuidado del Ojo” (SPCO) and was distributed to all persons who attended the educational sessions.

Educational session participants were also informed about the opportunity to receive a free dilated-eye screening exam from a qualified ophthalmologist on one of the screening days (Phase II). The project investigators, in collaboration with the local pharmacists in charge, identified participants (from among those who attended the educational sessions) at each pharmacy who met the inclusion criteria. To be eligible for the free screening exam, potential participants had to 1) be 21 years of age or older, 2) have type 1 or 2 diabetes mellitus (having been diagnosed within the least five years), and 3) either have no health insurance or have only the government of Puerto Rico’s health insurance (“Reforma de Salud”). Potential participants without a previous diagnosis of retinopathy, with a life expectancy shorter than 6 months, or who had private health insurance were excluded from the study. Participants with private health insurance were advised to visit their primary physicians for an appropriate referral or to directly visit the ophthalmologist of their choice for an annual eye assessment and any necessary follow-up care.

Participants identified as being eligible to receive a free eye exam were instructed to communicate with the appropriate pharmacist in order to set up an appointment for the exam,

each of which appointments took place at a convenient time from 8:00 AM to 5:00 PM on one of the available screening days. The pharmacists, in collaboration with the principal investigators, ensured that the patients selected for free eye exams were in compliance with the inclusion criteria.

Phase II - Screening-day Sessions

On screening days, each eligible participant received an ophthalmological assessment designed to evaluate his or her retinal condition relative to DR and, if such should be the case, identify undiagnosed DR. A private office beside the prescription area inside each pharmacy was made available for these examinations. Prior to their individual exams, the participants were informed about the study and then asked to sign an informed consent form provided by one of the principal investigators. Participants with low literacy skills could have the consent form read to them by one of the investigators after which all of their questions would be answered prior to their signing the form. In some instances, a participant’s relative was allowed to read the informed consent form to the participant and then, on behalf of the participant, was encouraged to ask any questions necessary to clarify any remaining issues; only upon the resolution of all of the participant’s concerns was a signature requested.

Upon arriving for their appointments on screening day and before receiving the ophthalmological exams, the participants were also interviewed by one of the principal investigators to obtain personal information, including sex, age, weight, height, and health insurance coverage. In addition, information about the current state of each individual’s health was also obtained, including a current blood pressure reading, a recent update on the type and duration of that person’s diabetes, which update collected such information as glucose control regimen, last fasting plasma glucose level, last glycosylated hemoglobin A1c, exercise history, nutritional plan, comorbidities, pharmacologic therapy, last ophthalmologist visit, and most recent dilated-eye exam. No personal or any other identifiers were collected by the investigators. After the interview was complete and the consent forms were signed, the participants received their ophthalmological exams.

Pharmacist Responsibilities

The pharmacists were responsible for 1) coordinating and promoting the open educational sessions to the community surrounding each pharmacy, especially to persons with diabetes and to local physicians in each of the communities who could refer their patients to the educational sessions, 2) helping to identify participants from the educational sessions who might benefit from a free ophthalmological assessment and who met the eligibility criteria, and 3) selecting areas within the pharmacy appropriate for conducting the educational sessions and the private ophthalmological assessments of patients.

Screening for Diabetic Retinopathy

Near and distance visual acuity (VA) with undilated pupils was measured using the standards for visual acuity testing: ETDRS (Early Treatment Diabetic Retinopathy Study) (12) and the Snellen visual acuity chart. A hand-held applanation tonometer was used to measure intraocular pressure and rule out glaucoma. A small-pupil direct panoptic ophthalmoscope (Welch Allyn™) was used for evaluating the posterior retina and macular area. A small-pupil binocular indirect ophthalmoscope (Mentor™) was used to examine the retinal periphery. Condensing lenses of 14 (posterior pole), 20 (equator), and 28 (periphery) diopter powers were also used. DR screening in participants with an unclear view of the retina was performed after topical dilation of the pupil (using tropicamide ophthalmic solution 0.1%) with a direct ophthalmoscope for the posterior retina and a binocular indirect ophthalmoscope for the periphery. The American Academy of Ophthalmology disease severity scale was used for the appropriate management and adequate referral of participants to their preferred eye care specialist. All participants were informed that there could be minor discomfort associated with the ophthalmological procedure before they were asked to sign the informed consent form (13).

Statistical Analysis

Measurements of central tendency including frequency, mean, and median, and a measurement of dispersion (standard deviation) were used to analyze demographic and health-history data, while the Statistical Package for the Social Sciences, Version XI, was used to analyze all other data.

Results

More than 600 people participated in the open educational sessions at the two community pharmacies. The session in Barranquitas marked the first time that a health festival had been coordinated by pharmacists, and more than 100 people participated. In Lares, the session was combined with a health festival known as the Festival de Salud Lareño, a yearly event since 2001, and more than 500 people attended. In addition to receiving information on DR at the educational sessions, participants also benefited from access to other health-related services, including blood glucose testing for diabetes screening, diabetes control strategies, blood pressure assessments, cardiovascular risk assessments, hearing exams, vaccinations, and HIV testing; participants also had the option of donating blood.

During the screening-day sessions (Phase II), 72 participants were assessed ophthalmologically by retinologist Dr. Raúl Pérez (40 at Farmacia San Jose in Lares and 32 at Farmacia del Pueblo in Barranquitas). The average age of the participants was 58 ± 13 years of age, 76% were females, and 96% had been previously diagnosed with type 2 diabetes mellitus. The average time since

the participants' initial diabetes diagnosis was 9.6 ± 7.4 years, and all of the participants had the government's health insurance.

Of the 72 participants evaluated, a total of 16 (22%) were diagnosed with DR (1 of the 16 had been previously diagnosed), and 2 of these cases were graded as being severe in both eyes. These participants were given copies of their ophthalmological assessments and referred to their preferred eye care specialists for treatment and continuing care. In addition, 6 were diagnosed with background diabetic retinopathy (BDR), 5 with diabetic macular edema (DME), and 1 with proliferative diabetic retinopathy (PDR) (Figure 1). Two patients were classified only as having diabetic retinopathy (DR), with the ophthalmologist offering no additional explanation or estimate of proliferative state. Furthermore, 14 patients were newly diagnosed with glaucoma, four of whom were also diagnosed with DR. Other diagnosed eye disorders included ametropia (2), pseudophakia (2), presbyopia (1), bilateral retinitis pigmentosa (1), age-related macular degeneration (1), and bilateral retinitis pigmentosa plus pseudophakia (1) (Figure 2).

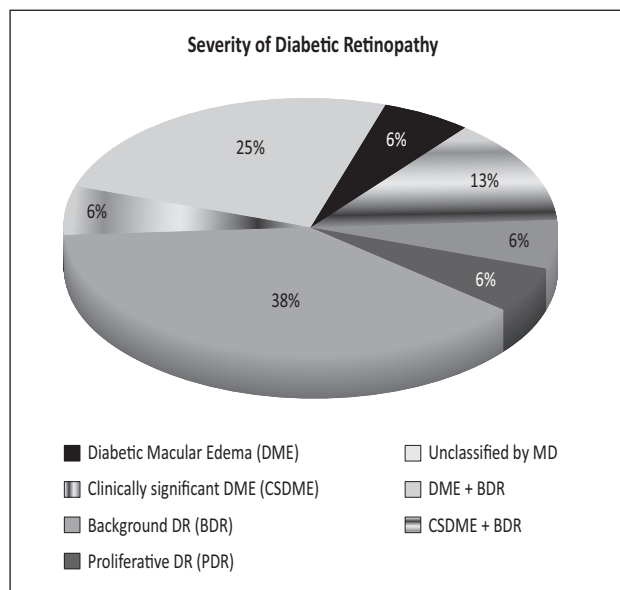


Figure 1. Type and severity of newly diagnosed DR.

The mean fasting blood glucose level for 68 of the participants was 172 ± 61.54 mg/dL or 9.6 ± 3.4 mmol/dL (N = 68); two participants had post-prandial glucose levels of 199 mg/dL (11.1 mmol/dL) and 497 mg/dL (27.6 mmol/dL), respectively, and 45 participants (63%) were able to easily access their most recent HbA1c values, the mean of which values was 8.21 ± 1.76%. These HbA1c values were obtained from the pharmaceutical care services records (31) at Farmacia San José in Lares. Five participants were able to obtain their records from Farmacia del Pueblo in Barranquitas, and 9 had acquired their medical records and their HbA1c levels from their primary care physicians in Barranquitas. HbA1c values were available for 11 of the 16 participants (69%)

who had been diagnosed with diabetic retinopathy, and all values were higher than 7%, with a mean of $8.38 \pm 1.01\%$.

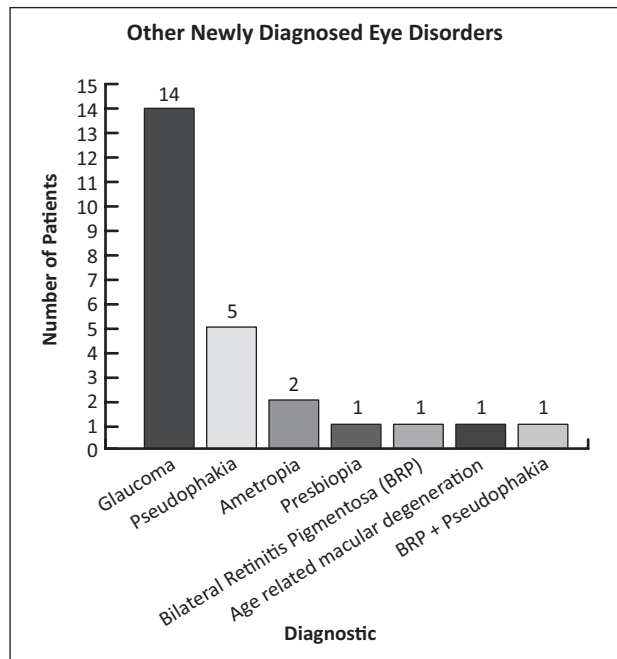


Figure 2. Eye disorders newly diagnosed besides DR.

Blood pressure was measured for all participants prior to their ophthalmological assessments. Mean systolic blood pressure was 140 ± 17.11 mmHg (N = 69), and mean diastolic blood pressure was 79 ± 8.03 mmHg (N = 69). Forty-eight participants (70%) had measured blood pressure values greater than 130/80 mmHg.

Of the 72 participants who received ophthalmological assessments, 47 (65%) were examined by an ophthalmologist for the first time and 45 (63%) received their first dilated-eye exam. Of the 25 participants who had visited the ophthalmologist prior to this study, 20 (80%) reported that they had never received an eye examination to detect DR. Almost none of the participants recognized the difference between an ophthalmologist and optometrist, nor did they know whether they had ever been evaluated for DR.

Each of the two participating pharmacies retained copies of both the ophthalmologist assessments and the health history questionnaires for later documentation of the project and so that they could follow up at a later time with all participants who had been diagnosed with a vision problem in order to ensure that they had received appropriate treatment to prevent vision loss.

Discussion

This study demonstrates that people with diabetes who control their glucose levels poorly are at high risk of having

undiagnosed diabetic retinopathy. All patients newly diagnosed with diabetic retinopathy had an HbA1c higher than 7% (7.3-10.7%), which is an indication of poor glucose control.

Many of the participants assessed in this study were not aware of the relevance of having their HbA1c checked regularly, especially those from the Farmacia del Pueblo in Barranquitas. Most participants from this region had never had their HbA1c tested and did not even know what the HbA1c value meant; those few participants who did recognize the meaning of HbA1c had been unable to control their glucose levels. This clearly speaks for the need to deliver local educational programs that address the complications that can attend diabetes and poor blood glucose control.

Participants evaluated at Farmacia San José, at which a pharmaceutical care service is available for local citizens with diabetes, were more knowledgeable about glucose values, HbA1c, diabetes complications, their health condition, and the medications they were taking. HbA1c values for project participants were more easily available at Farmacia San José than they were at Farmacia del Pueblo, but the comparison of HbA1c values from the two pharmacies showed little difference. Consistent with other measured parameters, blood pressure and certain other components of the participants' lipid profiles (from both pharmacies) were also not well controlled.

As previously stated, most of the participants in this study did not know the difference between an ophthalmologist and optometrist or whether they had ever been evaluated for diabetic retinopathy. This finding is significant and is of great concern, because it is essential that persons with diabetes visit an ophthalmologist annually for an evaluation of possible DR and other vision complications in order to ensure that they receive timely treatment to prevent vision loss.

An estimation of the impact of cost of services was not an objective of this study and was not done because these services are free for low-income residents of Puerto Rico with diabetes. It would be reasonable to include an assessment of the cost of such services in future studies so as to determine the viability of establishing these services (through local community pharmacies) for higher income island citizens with private health insurance.

Pharmacists can contribute greatly to the prevention of severe vision loss by promoting and conducting community education programs and by facilitating eye examinations for local citizens at risk for the development of diabetic retinopathy. Community pharmacies are the most visited healthcare centers in Puerto Rico, and a great opportunity is missed when we fail to use such sites to promote beneficial healthcare behaviors. Pharmacists are on the front line of health care, and with their frequent contact with local citizens, they are in a pivotal position to contribute to enhancing community awareness regarding the complications of diabetes and other chronic health conditions and to contribute

as well to the self-care behaviors that can maintain and improve the quality of life for all of the residents of Puerto Rico.

Collaborations between pharmacists and ophthalmologists have great potential to vastly decrease vision loss by creating greater awareness among those within the local population who suffer from diabetes of the potentially severe vision problems that are associated with poor glycemic control. And these collaborations serve as a model for other kinds of collaborations that could contribute to the more effective management of an array of chronic healthcare problems in Puerto Rico.

The community pharmacy is an excellent place to educate area citizens with diabetes about DR and to identify those with undiagnosed diabetic retinopathy and refer them to their preferred ophthalmologists for treatment and continuing care. The important role that the pharmacist can play as healthcare provider in the education, prevention, and detection of diabetes-related complications has been confirmed in this study. Further work is encouraged so that this service might be expanded to community pharmacies throughout Puerto Rico.

Acknowledgments

The principal investigators recognize the Pfizer Corp. for its contribution toward making this investigation possible. We also would like to acknowledge the following pharmacists for their help in coordinating the open educational sessions and the screening-day assessments: Rosa Wilma Ramírez, RPh, and Lourdes Ramírez, RPh, from Farmacia San José in Lares, and Nilda López, RPh, from Farmacia del Pueblo in Barranquitas. José Oriol Torres, PharmD, and Carla Marrero, PharmD, deserve to be recognized for their contributions to proposal development, research performance, and data assessment. Most importantly, we must “greatly acknowledge Dr. Raúl Pérez, Retinologist, for his tireless efforts on behalf of all of his patients.

Resumen

Objetivo: La retinopatía diabética está asociada al pobre control de la glucosa y es la causa más común de ceguera en los adultos. El propósito de este estudio fue demostrar que los farmacéuticos podrían desempeñar un rol importante en la detección de retinopatía diabética al identificar personas a riesgo de retinopatía diabética, educándolos sobre esta condición, facilitándoles un examen oftalmológico, y refiriendo a aquellos con desórdenes oculares para tratamiento y seguimiento por los especialistas. **Métodos:** El estudio consistió de dos fases en dos farmacias de la comunidad: una sesión educativa abierta y un día de evaluación. Una cita para la evaluación oftalmológica fue programada en cada farmacia. Se completó el historial demográfico y de salud. Los hallazgos fueron

enviados al médico del participante. **Resultados:** Setenta y dos pacientes fueron evaluados. La edad promedio fue de 58 años; 76% fueron mujeres. Dieciséis pacientes (22%) fueron identificados con retinopatía diabética y fueron referidos a su oftalmólogo preferido. Catorce pacientes fueron diagnosticados con glaucoma, 4 de éstos también fueron diagnosticados con retinopatía diabética. **Conclusión:** La farmacia de la comunidad es un excelente lugar para proveer educación sobre retinopatía diabética, identificar pacientes sin diagnosticar y referirlos a su oftalmólogo preferido. El rol del farmacéutico como proveedor de salud en la educación, prevención y detección de complicaciones de la diabetes ha sido confirmado.

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