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Research Article

Effectiveness in the Implementation of a Sectorial Diabetic Retinopathy Prevention Program in Hidalgo, Mexico

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Abstract

Objective: Assess the effectiveness of a diabetic retinopathy prevention program by evaluating the fundus of the eye of patients with diabetes mellitus (DM) in four selected health care centers that have a primary care physician trained in this procedure and who refers patients to secondary or tertiary care for adequate treatment to mitigate damage caused by retinopathy.

Material and Methods: This was a cross-sectional, descriptive study of a non-probabilistic convenience sample of patients in the program from centers in the cities of Actopan, Pachuca, Tizayuca, and Tulancingo in the state of Hidalgo, Mexico. Data were collected from clinical records.

Results: There were 453 patients, 78% women and 22% men. Mean age was 65 years and 81 patients had diabetic retinopathy. Mean duration of DM since diagnosis was 7 years. Comorbidities were found in 393 (86.5%); these were hypertension in 372, dyslipidemia in 14, and other pathologies in 7. According to triage 81 (17.8%) patients had retinopathy: 6 had low-risk proliferative retinopathy, 2 had high-risk proliferative retinopathy, 7 severe non-proliferative retinopathy, 14 moderate non-proliferative retinopathy, 52 mild non-proliferative retinopathy, and 372 without retinopathy. Mean glycosylated hemoglobin was 10.5% and a urine protein of 20 mg/dL, unique sample. A total of 59 patients were referred to secondary care.

Conclusions: The diabetic retinopathy prevention program and the control card have demonstrated their usefulness in the empowerment, diagnosis, and timely referral of patients.

Keywords: *Retinopathy; Diabetes Complications; Economic Burden*

Introduction

Chronic degenerative diseases occupy a prominent role because they have a long duration, are slowly progressive, and represent a high cost for patients, their family, and the health system. Among these, diabetes mellitus (DM) is an endocrine metabolic syndrome that has macrovascular, microvascular and neuropathic complications [1]. Its prevalence was estimated as 2.8% in the year 2000; and by 2030 it will be 4.4%. The total number of people with diabetes was 171 million in 2000; and by the year 2030 it is estimated to be 366 million [2].

Diabetic retinopathy (DR) is a common microvascular complication of DM. Elevated blood glucose levels induce structural, physiological, and hormonal changes that affect the capillaries in the retina. It is currently the main cause of blindness in developed countries in individuals between 20 to 74 years of age. In developing countries, DR represents 30% of retinal diseases in middle-aged adults. DR affects 20% of patients with type 2 diabetes at the time of diagnosis and its incidence increases with time (8% at 3 years, 25% at 5 years and 60% at 10 years, and up to 80% at 15 years) [3,4].

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Diabetes duration is considered the most important factor related to severity and prevalence of DR. Elevated blood glucose levels are considered the second most important risk factor since they directly affect the microcirculation in addition to increasing non-enzymatic protein glycosylation [5-7]. The risk factors for development of DR are high glycosylated hemoglobin (HbA1c) levels, a reduction in hematocrit, an increase in serum lipids, the duration of DM, the presence of microalbuminuria, and pregnancy [8,9].

Optimal management of glucose levels and hypertension reduces the incidence and progression of DR. Blood glucose control alone reduces the risk of DR in approximately 27%. Likewise, an adequate exam ensures timely detection and treatment and reduces vision loss [10]. Despite this, more than 30% of the population with diabetes has never had an ophthalmic examination [11].

The global prevalence of DR varies from 10% to 30% and its behavior in developed countries, such as the United States, has been moderate to severe in 32%. In Mexico, in states such as Durango, prevalence is 21.3% [12]; in Hidalgo, prevalence is 33.3% [13].

Research on the cost-effectiveness of ophthalmologic treatment in patients with DM has been performed, and in the United States, it is estimated at 75 million dollars. The annual cost to avoid blindness caused by non-proliferative diabetic retinopathy (NPDR) in a patient with type 2 DM is USD 966 *per capita*, and for conserving central vision caused by macular edema, USD 1,118 [12]. In Mexico, the prevalence of eye problems caused by DM is not precisely known but it is probably high; in fact, it is believed that the appearance of eye problems is an inevitable consequence of diabetes and disease duration is one of the most reliable predictive factors of retinopathy [14].

The policies in our country have not been continuous with regard to the prevention, detection and care of DR. Recently, specialized medical units (UNEMES, in Spanish) have been established for the treatment of non-communicable chronic diseases (overweight, obesity, cardiovascular risk and DM). The results of the National Survey of Health and Nutrition 2012 showed that 3 out of 4 patients with diabetes require greater control of their illness to reduce long-term complications, the most frequent were loss of vision in 47.6% (3 million) and retinal damage in 13.9% (889 thousand) [15].

The parameter of effectiveness in the detection of DR is an annual eye fundus examination; however, treatment is not included in the Universal Catalog of Health Services (CAUSES, in Spanish) of the Social Protection in Health System (SPSS in Spanish) due to budget constraints, despite the presence of an acceptable cost-effectiveness.

In clinical practice, the primary care physician infrequently examines the eye fundus or refers the patient to the ophthalmologist to prevent blindness. Nevertheless, these specialists are insufficient to offer treatment to patients with retinal damage. Thus, the importance of having the necessary equipment and training of primary care physicians and including in subsequent consultations a mandatory fundus examination in patients with diabetes, hypertension and pregnant women is evident, even if the rate of regression of DR after gestation or puerperium is high.

The Diabetes Retinopathy Prevention Program of the State of Hidalgo was designed to evaluate the eye fundus in patients with DM treated at health centers by primary care physicians trained in this procedure to make a timely diagnosis and refer the patient if necessary to secondary or tertiary care for proper treatment and to reduce the incidence and mitigate damage caused by DR. The program consists of:

a) Theoretical and practical training in eye fundus assessment by physicians from selected health care centers.

b) Installation of an ophthalmoscope so the physician can perform evaluations in patients with DM.

c) Triage for referral and counter-referral of patients for care.

d) Assessment of three patient parameters: Fundus, glycosylated hemoglobin, and proteinuria

e) Patient follow-up.

A patient diabetes control sheet was designed based on a stoplight system that visually indicates the eye fundus as without retinopathy, with non-proliferative retinopathy, and with proliferative retinopathy. Likewise, the control sheet shows glycosylated hemoglobin and microalbuminuria levels. If the information is within normal limits, it is registered as a green area, if a change is present, it is registered as a yellow area and if there is an evident abnormality, it is registered as a red area. In this way, patients and their families are aware of these conditions and monitor them more carefully; this was done to empower the patient about his/her disease. The patient is asked to mark on his control card the point that shows the result of the evaluation: fundus, glycosylated hemoglobin, microalbuminuria, so he/she can know in what area they are in. In this way, if the patient is in the green zone, he/she can indicate on the card an image of acceptance or if he/she is in the yellow or red zone, he/she will know that there are failures in glucose control or damage that is in development. In this case the image that they need to select shows concern (Figure 1).

Figure 1

To discover if the program works, the effectiveness of the DR prevention program was assessed by evaluating the fundus of the eye of patients with DM in four selected health care centers attended by a primary care physician trained in the procedure and who refers patients to secondary or tertiary care for adequate treatment to mitigate damage caused by retinopathy.

Material and Methods

This was a descriptive cross-sectional study of patients in the Sectorial Program of Prevention of DR in four healthcare centers in Actopan, Pachuca, Tizayuca and Tulancingo, Hidalgo. A non-probabilistic convenience sample of all patients included in the program was studied to determine the effectiveness of the program and to clinically characterize the population of patients integrated, determine the degree of retinal involvement with regard to time, and HbA1c and microalbuminuria levels.

Data were collected from the medical records that included a specific medical note on eye fundus assessment according to the following procedure: A drop of ophthalmic tropicamide/phenylephrine was applied in a darkened room 10 minutes before evaluation with an ophthalmoscope. An examination was then begun to detect changes, and finally a drop of 2% pilocarpine was applied to revert the mydriatic effect. To determine proteinuria and HbA1c, the rapid tests, Micraltest® (Roche Diagnostics Limited, Basel, Switzerland) and A1C NOW® (Polymer Technology Systems, Inc. Indianapolis, IN), respectively, were applied. The patients were given a control sheet for follow up and to empower, sensitize, and make them aware of their disease. Evaluated patients who according to triage required referral to an ophthalmologist were sent to a secondary care center.

A database was created in Microsoft Excel 2013 and the information was exported to SPSS version 18 for statistical analysis. Descriptive statistics with measures of central tendency and dispersion for quantitative variables was used; odds ratios and proportions were used for qualitative variables.

The protocol was approved by the Ethics and Research Committees of the Hidalgo Health Services, by the authorities of the Health Research Coordination Administration, and by the Jurisdictions of the Health Centers of the Hidalgo Health Services and the study was conducted in accordance with the principles of good clinical practice and the Declaration of Helsinki.

Results

Four hundred fifty-three patients with DM were included in the program: 164 (36%) from the municipality of Tizayuca, 100 (22%) from Tulancingo, 100 (22%) from Pachuca and 86 (19%) from Actopan. According to gender, 78% were women and 22% men (Figure 2). Mean age of the study population was 65 years. The prevalence of retinopathy was 17.8%, 81 patients and mean time of DM evolution was 7 years.

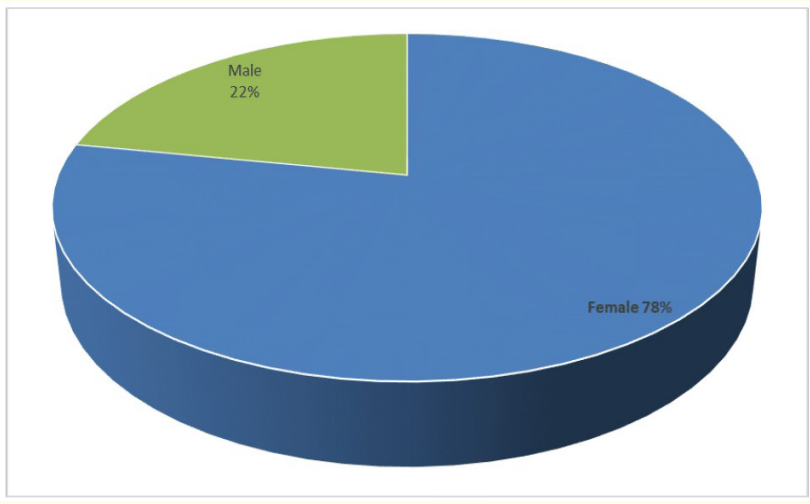

Figure 2: *Distribution of the study population according to gender.*

Of the total number of patients, 393 (86.5%) had a comorbidity. Hypertension in 372 (82.1%), dyslipidemia in 14 (3.5%), and other pathologies in 7 (1.7%) (Figure 3). Regarding the group of patients with diabetic retinopathy, 67 (82%) had hypertension, 29 (36%) had metabolic syndrome, 7 (9%) dyslipidemia and 56 (82%) another pathology.

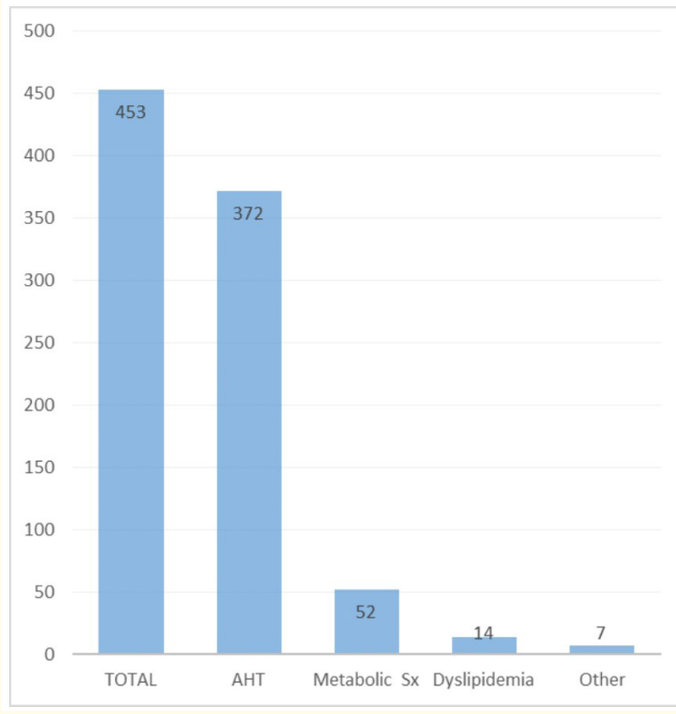

Figure 3: *Number of comorbidities present in the study population.*

According to the fundus assessment, 6 patients had low-risk proliferative diabetic retinopathy, 2, high-risk proliferative diabetic retinopathy, 7, severe non-proliferative diabetic retinopathy, 14, moderate non-proliferative diabetic retinopathy, 52, non-proliferative diabetic retinopathy, and 372 did not have diabetic retinopathy (Figure 4).

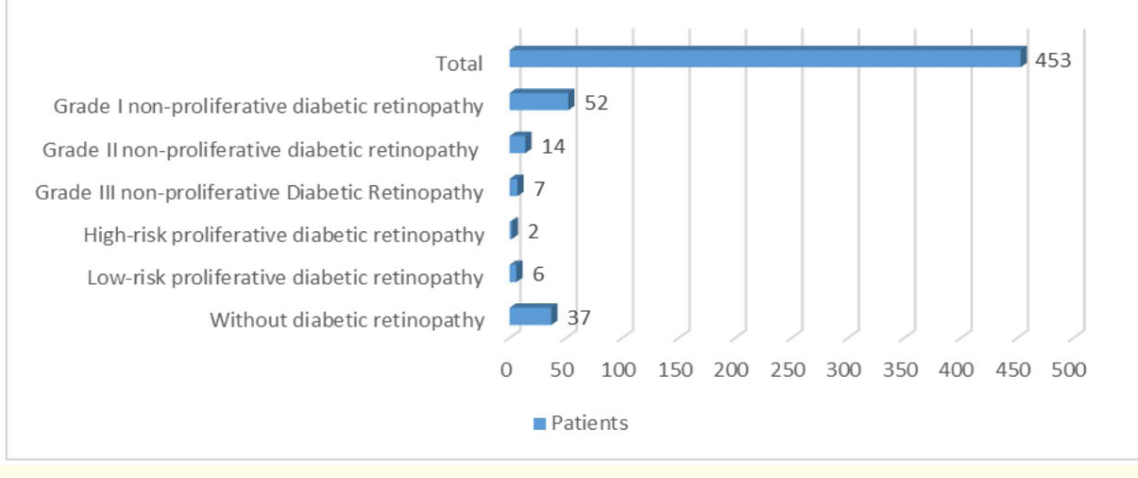

Figure 4: *Triage of patients according to type of retinopathy.*

Among the ophthalmologic findings were decreased visual acuity (determined with the Snellen Test), lesions around the macula, hyaloid hemorrhage, cataracts, retinal detachment, microaneurysms, and increased intraocular pressure (Table 1). In addition, patients had a mean glycosylated hemoglobin of 10.5% and a microalbuminuria level of 20 mg/dL (Figure 5).

Degree of retinopathy	n	Finding
Low-risk proliferative diabetic retinopathy	4	Decreased visual acuity; lesions surrounding the nacreous macula.
High-risk proliferative diabetic retinopathy	2	Decreased visual acuity
Grade III non-proliferative Diabetic Retinopathy	5	Hyaloid hemorrhage + cataract + retinal detachment
Grade II non-proliferative diabetic retinopathy	9	Cataract; hyaloid hemorrhage + cataract; cataract + microaneurysm
Grade I non-proliferative diabetic retinopathy	39	Retinal detachment; cataract; cataract + microaneurysm; cataract + increased intraocular pressure

Table 1: *Diabetic retinopathy findings in referred patients (N = 59).*

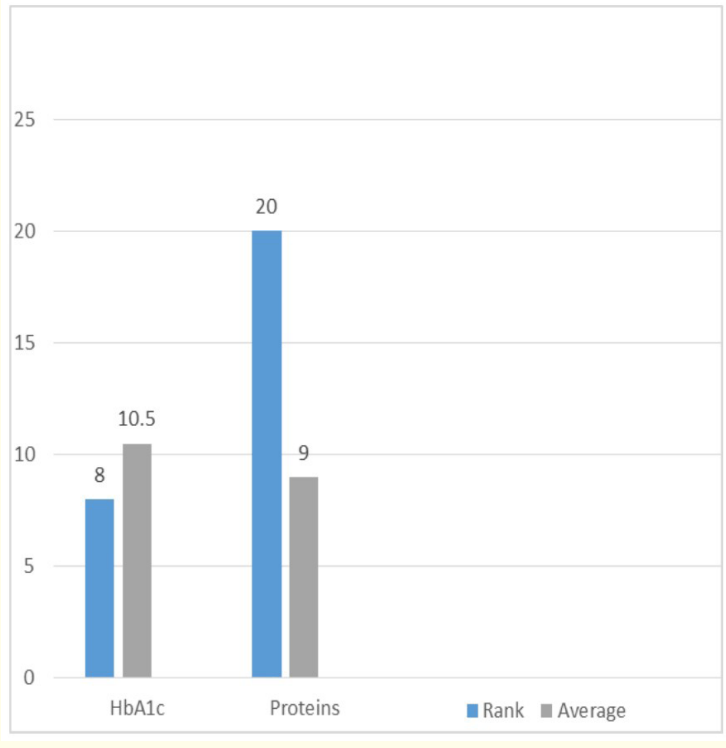

Figure 5: *Serum levels of HbA1C and level of urinary protein.*

The time of evolution of diabetes in patients in this study was from 7 years to 14 years and this was only in two patients (Figure 6).

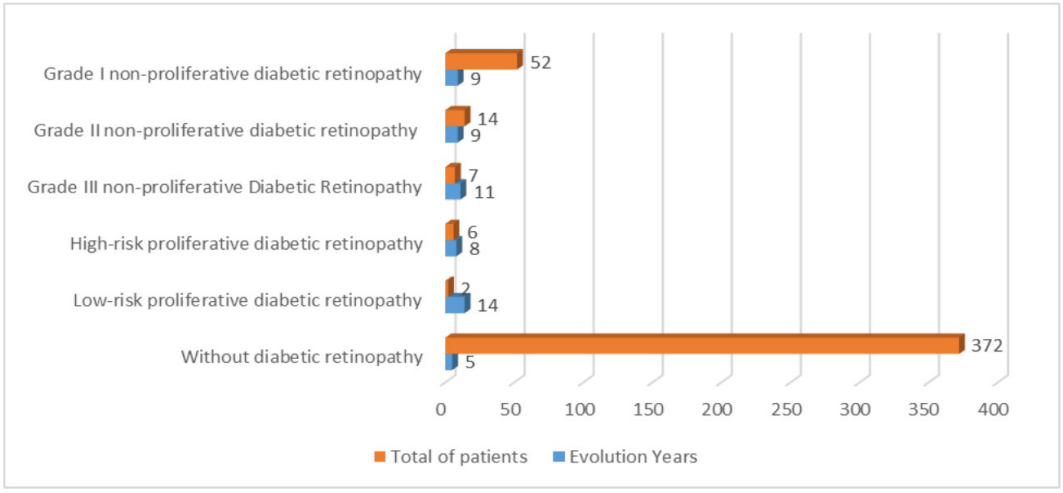

Figure 6: *Years of evolution with diabetes mellitus.*

A total of 59 patients were referred to the second level of care. So far there have been three successful cases of cataract surgery; patients who had lost vision and who, after surgery, were fully recovered (Figures 7 and 8).

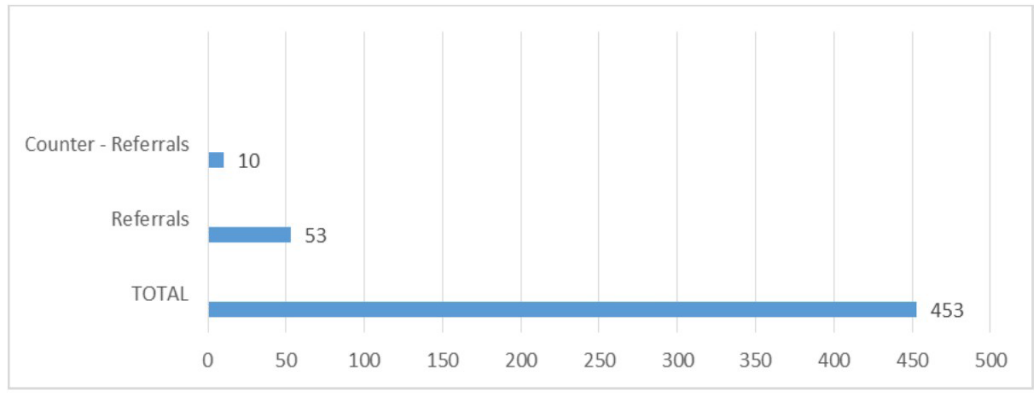

Figure 7: *Number of referrals and counter-referrals to secondary care.*

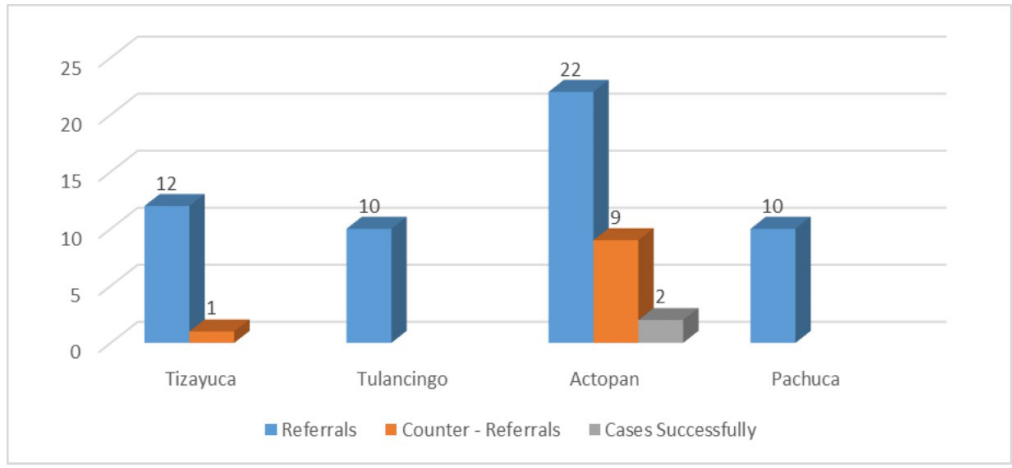

Figure 8: *Number of cases successfully treated after assessment and referral.*

Discussion

The Health Secretariat has declared DM an epidemiological emergency because of its high incidence in Mexico. It is one of the main pathologies with serious complications that represents a large part of the total expenditure of the health sector with DR being its most frequent and costly complication besides being one of the main causes of ophthalmologic consultation in tertiary care and the leading cause of preventable blindness and loss of visual acuity.

According to a study by Tudor., *et al*. in Latin American population, about 12.2% of the total expense of the health sector is for DR and the number of patients affected in Mexico is approximately 6.5 to 10 million [17].

Prado Serrano., *et al*. [18], in their study performed in the General Hospital of Mexico, mention that the prevalence of DR was greater in women, 71% were diagnosed with NPDR and 29% did not have this pathology. Our results also reflect a greater prevalence in women. The relationship with time of evolution pointed out by Tudor *et al* indicates that the probability of developing retinopathy is directly related to the time of disease evolution and deterioration. Our study had a mean time of evolution of DM of 7 years for the development of DR. This is in contrast with a study performed in Brazil where Romero., *et al*. [19] reported the appearance of DR in their population after 15 years of evolution of DM. The difference in the results of these authors could be related to poor glucose control of our patients despite the short time of evolution.

In a recent study performed by the Research Sub-Administration of the Health Services of Hidalgo in patients that attend diabetes clinics the prevalence of DR was 33.3%, a figure greater than that reported in the literature and in the country. Non-proliferative diabetic retinopathy (NPDR) was 29.9%, and proliferative diabetic retinopathy (PDR) 3.4% in patients with a mean age of 58 years. Of the total patients, 77.8% were women; regarding education, 38.5% were illiterate and 30.8% had a basic education. Mean venous blood glucose was 161.7 mg/dL. Mean disease duration was 9.9 years [16].

Another study, also carried out by the health services, identified that the level of knowledge that patients with diabetes have about their disease is very low and that this contributes to inadequate glucose control. This together with the process by which patients pass from a tanatological point of view, their loss of health and their permanence in a state of denial, anger or depression, hamper the empowerment of their disease and favors subsequent complications. It was also found that physicians do not perform an eye fundus exam and

they do not have adequate equipment (ophthalmoscope) in the medical units (health centers or diabetes clinics) and lacked sufficient knowledge in this procedure [16].

Due to these results, a second research project using a mathematical model was carried out to determine the progression of retinopathy by the year 2030. The results present a disturbing view since by 2030 DM will increase fourfold and therefore retinopathy. In the case of non-proliferative retinopathy, it will increase twofold and proliferative retinopathy 52 times. Furthermore, it is important to consider other associated complications such as cataracts and glaucoma. This means that health service demands will increase more than the possibility of providing care [17].

This knowledge will be very useful for designing plans and programs for preventing blindness caused by DR and for identifying the needs of care and health services access.

With regard to the mean age of our patients with DR (65 years), it is an older population, which due to greater systemic deterioration, could favor the appearance of complications such as hypertension, dyslipidemia and different degrees of DR.

Considering that macular lesions are one of the main clinical complications and the main cause of blindness in 50% of patients with DM, the results of this study have been of vital importance since the use of the ophthalmoscope and training primary care physicians for this study have permitted early detection of findings that can be treated to prevent worsening of DR in affected patients.

The prevalence of retinopathy was not very high probably due to the short duration time of the disease.

A small number of cases of DR of different degrees were found in this study (17.6%). This could be due to the short time of evolution of diabetes in patients in this study (7 years). The longest time of evolution was 14 years and this was only in two patients. The problem may also have been underdiagnosed, taking into account that the Prevention Program is only in its first year of operation and that it is necessary for the physicians who evaluate the patients to gain more experience in the fundus procedure and in the identification of retinal changes since the number of cases is low compared to findings from other studies such as in Honduras in 2016, which had a prevalence of 19% with an evolution of more than 15 years [20] or that of Teruel Maicas en Girona, Spain which found a prevalence of 30.6% [21]. Likewise, in Costa Rica, Martínez-Arguedas and Marchena found results similar to ours regarding prevalence (16.4%) and predominance in women [22]. Other studies had a prevalence of 70.9%, but these stated that patients with type 1 and 2 DM had developed DR in the first 10 years of evolution; this was probably related to very poor control of blood glucose levels [23].

In some studies with a mean time of evolution of 15 years, 80% of patients had DR and positive microalbuminuria [24], a finding similar to our results where all the patients who were diagnosed with some type of retinopathy had microalbuminuria with a mean of 20 mg/dL.

The patient control card showed us that the patients, by marking their own results, identified their status in the three parameters that were measured; if they were in the yellow or red areas, they showed concern and asked more questions about how to get back into the green zone. Those who were in the green zone were proud of controlling their levels and had a good state of health. This was not only reflected in treatment compliance but also in changes in eating habits, since they said they had more interest in their nutrition. Likewise, other patients who did not have knowledge of the importance of good blood glucose control, stated that with this visual support it would be easier for them to maintain or reach good control, since it was difficult to understand the figures given by the attending physician.

The control card for the patient was useful and the patients reported that it contributed to easier identification of their metabolic control which improved their mood by visually identifying a progressive improvement (Appendix 1).

In this way, patients are more aware of their glucose levels and their general state of health, although it is necessary to reinforce the use of the control card and include the family in this control. This is very important as a support network for the patient.

The lack of empowerment of patients regarding their disease, poor hygiene–dietetic habits, and genetic factors of the population are also of utmost importance for prevention; this is why DM and DR continue to increase. Therefore, it is important to have a Prevention Program that allows a timely diagnosis, spreading information in the population, and effective treatment in the case of cataracts and glaucoma, to stop possible complications such as blindness and with concomitant savings since the cost of treatment is higher as the disease progresses, and with a high economic and social impact on the health system and the population in general.

The results of this characterization represent only a part of the population of Hidalgo that are attended in primary care clinics, since the study group included was limited to only four municipalities of the state. This represents a limitation for generalizing results in the rest of the state and for determining the total prevalence in the state, due to budget limits. However, It is hoped that the results of this study will represent the beginning of a solution that will allow this strategy to be consolidated with the development of government policies that will provide continuous training and basic equipment for primary care clinics for implementation of the program at the state level and with it prevention that reduces this health problem and mitigates damage.

The economic impact of diabetes and its complications, such as retinopathy, is seen as the pressure that generates cost in medical care [25]. However, diabetes and its complications not only affect medical care costs but also the individual´s ability to work and his/her productivity. This affects the family´s income and the worker´s contribution to the country's production. Therefore, it is important to consider the economic burden of retinopathy, which comprises the direct costs associated to medical care expenses (services and drugs or procedures) and indirect costs, such as those related to the effect that it has on disability and on the patient's participation in the workforce. In 2013, the economic burden of diabetes was estimated at 362,859.82 pesos or 2.25% of GNP. If current conditions continue, it will be 2.62% of GNP by 2018. With regard to cost of care of retinopathy complications, it was calculated in 2013 that annually retinal damage and macular edema cost $ 6,529 pesos MXN per patient, a cataract $11,260 pesos MXN per event, and glaucoma $ 9,644 pesos MXN per event. This gives a total in Mexican population of $ 1,626.1 million pesos for the care of retinopathy in its different stages; for cataracts $ 18,531.1 million pesos, and for glaucoma $ 9,509.2 million pesos [25].

That is why, considering this very important information, a timely diagnosis and treatment are necessary to mitigate damage and reduce direct and indirect costs of this complication.

Conclusions

Despite the short implementation time, the Sectorial Program for the Prevention of Diabetic Retinopathy has been useful for early diagnosis and has contributed to the prevention of DR.

The ophthalmologic examination performed by trained primary care physicians as an action aimed at timely diagnosis and treatment aims to reduce health system costs, since there are not enough ophthalmologists to care for all patients, and provide patients with at least one annual consultation as proposed in official standards. However, it is necessary to widen the program in the entire state to be able to identify urgent cases to provide care, reduce alterations in visual acuity and the incidence of blindness in individuals with diabetes, ensuring adequate coverage for the population that suffers this disease.

Likewise, it is necessary to prepare state hospitals to provide secondary care to patients and to implement in the medium term an Ophthalmologic Medical Unit that provides tertiary care so patients do not have to travel to Mexico City.

The patient control card demonstrated its usefulness and easy understanding for the patient and family. This empowered the patient to actively manage the disease obtaining better metabolic control and therefore fewer complications, and a decrease in cost of care.

It would be convenient to extend the program to all State Health Centers, training physicians and providing them with the equipment and supplies they need for assessments.

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