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Teleophthalmology: a strategy for timely diagnosis of sight-threatening diabetic retinopathy in primary care, Concepción, Chile

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Abstract

• **AIM:** To estimate the prevalence of diabetic retinopathy (DR) in a diabetic population of the public health system.

• **METHODS:** This non-experimental, descriptive and cross-sectional study, with no direct control over the variables analysed, was carried out by the Telemedicine Unit of the University of Concepción (TELMED) and the Family Health Centers (CESFAM) of the Health Service Concepción, Chile, among a population of 7382 diabetic patients of the public health system, from October 2014 to June 2015. Two digital images for each patient's eyes were obtained and uploaded to the TELMED tele-ophthalmology platform. The images were remotely evaluated by a retina expert ophthalmologist for diagnosis. Treatment and a referral (if required) were recommended, and an individualised report for each patient was sent to the place of origin.

• **RESULTS:** The prevalence of DR in this study was 14.9%. Of these, 48.7% had mild non-proliferative DR (NPDR), 30.8% moderate NPDR, 15.9% severe NPDR, and 4.6% proliferative DR. Of the patients with DR, 17.8% were referred for fluorescein angiography, 4.3% for panretinal photocoagulation, 1.2% for vitrectomy, and 0.4% for cataract surgery.

• **CONCLUSION:** The use of telemedicine allowed an increased screening coverage for DR in diabetic patients. The different types of DR were detected in a timely manner, decreasing waiting times due to the lack of specialists in ophthalmology in the public health system.

• **KEYWORDS:** ophthalmology; teleophthalmology; diabetes mellitus; diabetic retinopathy; telemedicine

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INTRODUCTION

There are 170 million people worldwide with diabetes and by 2030 this figure could reach 440 million^[1]. Diabetic retinopathy (DR) is a leading cause of vision-loss globally^[2]. The prevalence of DR is related to the prevalence of diabetes mellitus (DM).

The latest (2016) update of the clinical guidelines of Diabetic Retinopathy of the Pan-American Association of Ophthalmology (PAAO), the Vision 20/20 initiative by the International Agency for the Prevention of Blindness (IAPB) Latin America, and the International Council of Ophthalmology (ICO) indicate that the prevalence and incidence of DR is increasing^[3], and by 2030 the number of cases will be doubled. DR is the leading cause of blindness in the working age group (20-74y)^[4].

The prevalence of DM in Chile is 11%^[5], which represents 11% of the adult population between 20-79 years of age^[6]. Studies reported by the National Health Survey (ENS) in Chile have shown that, at diagnosis of type 2 diabetes (T2DM), 20% of patients have some degree of DR. Only 34.8% of the people with diabetes have ever received a dilated fundus examination by an ophthalmologist^[4]. Therefore, it is suggested that this situation be countered with national programmes for the early detection of DR.

Some studies promote tele-ophthalmology programmes as an alternative to reach people with diabetes. They have adequate sensitivity and specificity for the diagnosis of DR, increasing coverage to those most at risk. International experience has shown the effectiveness and timeliness of telemedicine in the

detection of DR. In England, Scanlon^[7] concluded that two photo shots with pupil dilation was an effective high sensitivity and specificity screening method for DR.

A study in Chiapas, Mexico, evaluated 2864 of 50-year-old or older patients diagnosed with diabetes or with a random blood glucose level >200 mg/dL. Patients with diabetes were assessed for DR using dilated clinical examination (direct and indirect ophthalmoscope) and one dilated digital fundus 45° photograph per eye (graded by an ophthalmologist during the survey and re-graded by a retinal specialist) following the Scottish DR grading protocol^[8].

In countries, such as England, every year a two-field digital mydriatic photographic examination is offered to all people with diabetes from the age of 12. In 2015, 2.14 million people were examined. Thanks to this programme, in England, DR is no longer the main cause of certifiable blindness in the working-age population^[9].

In Chile, the Ministry of Health (MINSAL) incorporated the screening strategy for retinopathy in controlled diabetic patients. The MINSAL, in its Clinical Guidelines for Diabetic Retinopathy, recommends a dilated funduscopy with examination of the posterior pole using slit-lamp biomicroscopy every 2y in T2DM by an ophthalmologist or screening with mydriatic and nonmydriatic digital retinal imaging^[10]. According to the MINSAL, the photographs must be taken by a Medical Technologist specialized in ophthalmology.

Statistics from the Biobío Regional Health Secretariat in 2015 show that the total population from the communities included in this screening strategy was 669 549 from which 3.0% came from rural areas, 42% were male, and 58% were female. The diabetic population reported was 27 734 people^[11].

In the Biobío Region, the Telemedicine Unit of the University of Concepción (www.telmed.udec.cl) aims to promote and develop telemedicine in different work areas through a multidisciplinary team, including medical specialists, health professionals, engineers, administrative staff, and undergraduate students by using Information and Communication Technologies (ICT) in education, clinical care, and research.

The objective of this study was to estimate the prevalence of DR as a result of the implementation of a telemedicine system led by TELMED for the detection of DR in patients of primary health care centres of the public health system in Concepción, Chile, who had no timely access to face-to-face attention with an ophthalmologist.

On the basis of the studies analysed, it was decided to use a two-field staged mydriasis (fields centred on the disc and the macula) for this investigation.

SUBJECTS AND METHODS

Ethical Approval The study was approved by the Concepción Health Service, Chile, based on the ethical principles for

medical research involving human subjects of the Helsinki declaration

Methods The research was carried out through a non-experimental, descriptive and cross-sectional study, with no direct control of the variables analysed. A tele-ophthalmology strategy was implemented in association with the Health Service Concepción, helping public primary care users from Concepción, Coronel, Lota, Chiguayante, San Pedro de la Paz, Florida, Santa Juana, and Hualqui. Patients attended one of the five Primary Ophthalmological Care Units (UAPO), which were fitted with non-mydriatic retinal cameras (Canon CR-2 Digital Non-Mydriatic Retinal Camera and Kowa) and access to a web-based platform to store and forward retinal images.

The sample consisted of a diabetic population of 7382 patients from the public CESFAM (Family Health Care Centres) of the Health Service of Concepción, Chile.

Screening Procedures Over 8mo (from October 2014 to June 2015), TELMED evaluated and reported on 7382 patient image sets from the Family Health Care Centres of the Health Service Concepción.

In this process, we used our web-based platform to share, store, and visualise the photographs. A medical technologist took the pictures at the Health Care Centre and provided all relevant medical history of patients. An ophthalmologist from the Faculty of Medicine accessed this information remotely through our web-based platform for diagnosis and referral.

The medical technologist identified the patient by entering the relevant details in the web platform and then measured and recorded the ocular tension and the visual acuity. Two photographs were taken for each eye (a macular centred and a disc centred field) using staged mydriasis. In most cases, the non-mydriatic photographs were evaluated by a medical technologist to assess whether they were adequate. For those who did not produce complete vascular visualisation in the photograph, the technologist proceeded to dilate the pupils with tropicamide 1% and the retina was re-photographed after 15-20min.

An authorised ophthalmologist from the University of Concepción, accessed the web platform, downloaded and visualised the photos to inspect them. For the digital images to be analysed, they had to comply with two quality standards. The ophthalmologist determined whether an image was non-gradable by using the following criteria: 1) In the macular field, the small vessels in the foveal area needed to be visible; 2) In the disc field, the small vessels around the disc needed to be visible. If a patient had non-gradable images after dilatation, they were referred to an ophthalmologist from the UAPO for further examination.

With the images suitable for grading, it was determined whether the patient had any degree of retinopathy. The

diagnosis criterion was some degree of DR in at least one of the patient's eyes. For the classification of the level of retinopathy in diabetic patients, the diagnostic criteria of the Early Treatment Diabetic Retinopathy Study Research Group (ETDRS), updated in the 2011 Clinical Practice Guide for Diabetic Retinopathy, were used^[11]: 1) no retinopathy; 2) mild non-proliferative DR (NPDR); 3) moderate NPDR; 4) severe NPDR; 5) proliferative DR.

A report was produced on each individual screened and sent to their respective UAPO for clinical management of the patient. Details were collected regarding the type of diabetes, treatment (medicine and diet), age, gender, hypertension history and other pathologies (e.g. nephropathy, dyslipidaemia, and diabetic foot problems).

If the Ophthalmologist at the University of Concepción graded the images as requiring referral, he informed the Primary Care Unit and the responsibility for referral laid with the Primary Care staff. The ophthalmologist at the University of Concepción recommended referral in patients whose images showed a level of moderate NPDR or a higher level of vision-threatening DR.

Statistical Analysis The statistical analysis focused on estimating the prevalence of DR in the diabetic population. The data of the study was input into an Excel database and analysed using R Software version 3.5.1. For quantitative variables, the mean, standard deviation, minimum and maximum were calculated. For qualitative variables, absolute and relative frequency percentage were calculated.

RESULTS

The tele-ophthalmology programme began in October 2014 and this study was carried out over an 8-month period. The total number of patients screened was 7382 accounting for 26.4% of the diabetic population under treatment who are beneficiaries of the five UAPO (Primary Ophthalmological Care Units). From this population, 6784 produced gradable images accounting for 91.9% of the sample (65.4% female and 34.6% male). For patients with gradable images, the age distribution was listed in Table 1. The mean age was 61y with a standard deviation of 9.8y.

In the 6784 people screened, the duration of diabetes was: less than 10y 68.3%; between 10 and 20y, 23.7%; over 20y, 7.5%; and 0.6% not reported. In most cases, the treatments were oral hypoglycaemic agents (68.5%), insulin (15.9%), and only diet (2.8%).

Comorbidities In relation to comorbidities, some of these patients suffered from more than one of these conditions (Table 2).

Prevalence of Diabetic Retinopathy The prevalence of DR for the study group was 14.9% (Table 3).

Of the 1008 patients, type of retinopathy rate was listed in Table 4.

Table 1 Age distribution n (%)

Age range	Values
<25y	37 (0.5)
25y-44y	419 (6.2)
45y-64y	3806 (56.1)
>64y	2517 (37.1)
Not informed	5 (0.1)
Total	6784 (100)

Table 2 Comorbidities rate n (%)

Comorbidities ^a	Values
History of AHT	3963 (58.4)
History of dyslipidaemia	1958 (28.7)
History of nephropathy	63 (0.9)
History of foot problem	48 (0.7)

^aA patient may have a history of more than one pathology.

Table 3 DR rate n (%)

DR classification	Values
No apparent retinopathy	5776 (85.1)
Any grade DR	1008 (14.9)
Total	6784 (100)

Table 4 Types of DR rate n (%)

DR classification	Values
Mild NPDR	491 (48.7)
Moderate NPDR	311 (30.8)
Severe NPDR	160 (15.9)
Proliferative DR	46 (4.6)
Total	1008 (100)

Duration of Diabetes and Degree of Retinopathy With respect to the number of years with the disease and the degree of retinopathy, the percentages increased as time passed; these account for 8.8% of patients less than 10y with diabetes, 26.7% of patients between 10 and 20y with diabetes; and 40.1% of patients more than 20y with diabetes.

Of the patients with recorded duration of diabetes (n=6746) we found that patients less than 10y with disease (n=413), 55.8% (n=227) presented mild retinopathy; 28.5% (n=116) moderate retinopathy; 14.5% (n=59) severe retinopathy; and 1.2% (n=5) proliferative retinopathy.

Of the patients with recorded duration of diabetes between 10 and 20y (n=500), 44.8% (n=224) presented mild retinopathy; 33.6% (n=168) moderate retinopathy; 15.8% (n=79) severe retinopathy; and 5.8% (n=29) proliferative retinopathy.

In patients with recorded duration of diabetes over 20y (n=95), 38.9% (n=37) presented mild retinopathy; 26.3% (n=25) moderate retinopathy; 22.1% (n=21) severe retinopathy; and 12.6% (n=12) proliferative retinopathy.

Degree of Diabetic Retinopathy Diagnosed Of the 1008 patients diagnosed with some degree of DR, 17.8% were referred for fluorescein angiography, 4.3% for panretinal photocoagulation, 1.2% for vitrectomy, 0.4% for cataract surgery, and 76.3% remained in primary health care to continue with their usual controls according to the Guidelines by MINSAL, Chile.

DISCUSSION

DM has become a global epidemic and one of the main causes of blindness among working-age adults. According to estimates of the World Health Organization (WHO), this disease will be the seventh cause of death by the year 2030, especially in developing countries. At present, DM is estimated to be the cause of blindness in 4.8% of the 37 million blind people around the world^[12-13].

Teleophthalmology is practiced in much of the world to increase access and coverage of patients and prioritise clinical care. Several studies show that teleophthalmology produces the same clinical results as the traditional face-to-face ophthalmological method^[14].

In this study, of the patients with type 2 diabetes ($n=6701$) with less than 10y with the disease, 8.8% had some degree of DR; between 10 and 20y, 26.5%; and of those who had more than 20y with the disease, 39.5% had DR. In the case of patients with type 1 diabetes ($n=45$) with less than 10y with disease, 7.4% presented some degree of DR; between 10 and 20y with the disease, 42.9%; and of those who had more than 20y of evolution of the disease, 75.0% presented some degree of DR.

Vision-threatening DR is the cause of 8% of legal blindness across the world. Studies in Latin America have shown that in 1.5% of the cases in Colombia and 15% in Brazil, the cause of blindness was related to DR^[3].

A study in Chile carried out between 2003 and 2006 showed that between 6.3% and 7.5% of the population has DM, being most prevalent in those over 44 years old, reaching 15.8% in those over 65 years old. Furthermore, it is related to the population at the lowest socioeconomic level^[4,10].

In another study in the United Arab Emirates, it was shown that 95 out of the 1024 patients examined had some type of DR. The incidence rate of DR in this study was 9.27%. The age ranged between 24y and 77y with an average age of 50.62 ± 10.13 y. The average duration of diabetes was 12.77 ± 6.57 y. In total, 165 eyes of 95 diabetic people had some type of DR. The distribution of the degree of severity of DR in 165 eyes was: mild NPDR in 114 of 165 eyes (69.09%); moderate NPDR in 32 eyes (19.39%); severe NPDR in six eyes (3.64%); and proliferative DR in 13 eyes (7.88%)^[12].

Another study conducted in the population of patients of Concepción in 2012, showed that out of 17 038 cases

diagnosed with DM, 64.1% were women^[15]. This difference may occur because females account for the highest number of medical consultations in the population over 65 years of age in primary care services in Chile.

The tele-ophthalmology programme in Concepción, Chile, included a funduscopy study in 6784 patients that accounted for 26.4% of the total population of diabetic patients of the five UAPO units of the Public Health Service^[16]. The female/male proportion was 30.8% more females as opposed to a Spanish study in 2012 where the population was 56.46% males and 43.54% females^[17].

However, when doing an analysis by sex, in our study, 13.1% of women presented some type of retinopathy while 18.1% of men did.

This telemedicine screening programme allowed the evaluation of more than a quarter of the people with diabetes in the Primary Ophthalmological Care Units of the Primary Care Health Service of Concepción and surrounding areas.

Out of 6784 patients who were successfully screened (with adequate images), 1008 patients (14.9%) had some DR. Of these 1008 patients, 48.7% were found to have mild NPDR, 30.6% moderate NPDR, 15.9% severe NPDR, and 4.6% proliferative DR. Those considered at risk of vision loss accounted for 7.7% of the original 6784 patients with moderate NPDR, severe NPDR and proliferative DR.

Our results have shown that the majority of the population with diabetes who attended the screening programme were 45-64 (56.1%) or over 64 (37.1%) years old which is in keeping with the age group of the population. However, the results also showed that the attendance figures were much higher in females (65.4%) than in males (34.6%), which is not in keeping with the population characteristics. There are slightly more women than men living in Chile (52.4% vs 47.6%) and more women than men in the 45-64 age group are diabetic (prevalence 19.3 vs 14.4) but in the over-65 group fewer women than men are diabetic (prevalence 22.8 vs 29.9). The reason for the large disparity between men and women attending this screening programme is probably because women in Chile are more likely to attend a public health screening programme than men. This situation will be studied in greater depth in later studies. Patients not diagnosed with DR were referred to face-to-face care.

This screening programme shows the need for timely and appropriate referral of these patients, 7.7% of whom are at significant risk of vision loss and blindness. Tele-ophthalmology emerges as a tested and validated tool in Chile and in the world in the investigation of the DR, and its main indicator of success is its capacity to obtain an early and timely diagnosis of severity, especially in patients at high risk of blindness.

Based on the results obtained in this study, it is suggested that the coverage of tele-ophthalmology in the public health service in Chile be increased, to contribute to the timely detection of patients at risk of blindness, due to risk factors associated with diabetes.

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