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Cost-Effectiveness of a Telemedicine Optometric-Based Assessment for Screening Diabetic Retinopathy in a Country with a Universal Public Health System

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Abstract

Objective: To determine the cost-effectiveness of a new telemedicine optometric-based screening program of diabetic retinopathy (DR) compared with traditional models' assessments in a universal European public health system.

Methods: A new teleophthalmology program for DR based on the assessment of retinographies (3-field Joslin Vision Network by a certified optometrist and a reading center [IOBA-RC]) was designed. This program was first conducted in a rural area 40 km from the referral hospital (Medina de Rioseco, Valladolid, Spain). The cost-effectiveness was compared with telemedicine based on evaluations by primary care physicians and general ophthalmologists, and to face-to-face examinations

conducted by ophthalmologists. A decision tree model was developed to simulate the cost-effectiveness of both models, considering public and private costs. The effectiveness was measured in terms of quality of life.

Results: A total of 261 patients with type 2 diabetes were included (42 had significant DR and required specific surveillance by the RC; 219 were undiagnosed). The sensitivity and specificity of the detection of DR were 100% and 74.1%, respectively. The telemedicine-based DR optometric screening model demonstrated similar utility to models based on physicians and general ophthalmologists and traditional face-to-face evaluations (0.845) at a lower cost/patient (€51.23, €71.65, and €86.46, respectively).

Conclusions: The telemedicine-based optometric screening program for DR in a RC demonstrated cost savings even in a developed country with a universal health care system. These results support the expansion of this kind of teleophthalmology program not only for screening but also for the follow-up of diabetic patients.

Keywords: diabetic retinopathy, screening program, telemedicine, optometrist, cost-effectiveness, retinal images, European country

Introduction

The number of people with diabetes mellitus worldwide has surged from 108 million in 1980 to 422 million in 2014.¹ In 2021, there were 529 million (95% uncertainty interval 500–564) people living with diabetes worldwide, and the global age-standardized total diabetes prevalence was 6.1% (5.8–6.5).² Diabetic retinopathy (DR) is a chronic and progressive retinal disease, characterized by neuronal and

small vessel damage with subsequent exudation and ischemic lesion affecting patients.^{2,3} Recent studies have estimated that globally approximately 103 million adults have DR, and this prevalence is projected to increase up to 160 million by 2045.⁴ This complication affects approximately 22% of the diabetic population and is considered the primary cause of blindness in the working-age population.⁴

The American Diabetes Association recommended that all patients with diabetes undergo a dilated fundus eye examination at least once annually.⁵ Traditionally, retina specialists and general ophthalmologists have conducted face-to-face screening examination for detecting and grading DR. However, with the development of telecommunication and retinal imaging systems, this trend is changing to telemedicine-based systems^{6,7} that enables patients to be assessed by a remotely located specialist. Although its initial purpose was to provide medical coverage to remote areas, teleophthalmology is an effective tool for managing prevalent, chronic, and relatively asymptomatic conditions, thereby contributing to the sustainability of public health systems.⁸

Telemedicine screening for DR can be conducted by primary care physicians (general practitioners [GPs]), nurses, general ophthalmologists, and other health care professionals.⁹ There is a consensus that telemedicine-based DR screening systems are cost-effective, particularly for low-income patients and in rural areas.^{10,11} However, most of these evaluations have been conducted in developing countries or among rural populations.^{12–14} In Spain, a country with a universal and efficient public health system, there currently is no unified national plan for DR screening, although some autonomous regions have established their own programs. These programs can be based on GPs, nurses, and ophthalmologists interchangeably.¹⁵ Nonetheless, costs could potentially be reduced by incorporating trained nurses for capturing images and optometric readers into these programs. Moreover, doubts may remain about their real value in a fully developed health system, with ophthalmology departments in hospitals and specialty centers, and the degree of acceptance of these technologies by patients.

The Instituto Universitario de Oftalmobiología Aplicada (IOBA) of the University of Valladolid, Valladolid, Spain, implemented a reading center (RC) in 2013 (IOBA-RC), because it was needed for a multistate project financed by the European Union in its 7th Framework Program (Project number:279075, EUDRA-CT: 2013-000418-39).¹⁶ After that experience, we included optometrists into DR screening to address the requirements of the Regional Health System (Gerencia Regional de Salud de Castilla y León, Sacyl). To the best of our knowledge, the IOBA-RC is the only such center in Spain. This follows the model used in the United Kingdom,¹⁷ which is based on images

captured by nonmedical trained personnel, with the initial classification conducted by a certified optometrist. However, in some regions outside of Spain, such as Canada, the analysis of extending public health insurance coverage to include DR screening by optometric services showed the cost-effectiveness from the perspective of the health care system.¹⁸ To date, no study has assessed the cost-effectiveness of the role of certified optometrists within a physical RC.

The aim of this study was to compare the efficacy and cost-effectiveness of a telemedicine DR screening program that incorporated optometrists in an RC with traditional telemedicine screening involving a GP and a general ophthalmologist and with traditional face-to-face examinations in a rural area of Valladolid.

Methods

DR TELEMEDICINE SCREENING PERFORMED BY IOBA-RC

Fig. 1 is the flowchart followed by diabetic patients within the DR screening program at IOBA-RC. *Fig. 2* shows the imaging protocol that follows the Joslin Vision Network system,¹⁹ and captures three standard 45-degree retinal images of each eye (encompassing the optic disc and macula [macular-centered field], the retinal area nasal to the optic disc [nasal field], and the superotemporal vascular arcade [superotemporal field]) along with an image of the fundus reflex focused on the pupil to assess the presence of opacities.

The images were transmitted to the IOBA-RC where they underwent a two-level evaluation. The first level involves an initial reading by certified optometrists, who classified the images into three categories: 1) not evaluable (due to the photographer taking an incorrect image with poor quality, opacities in the anterior pole, or insufficient pupillary size), in which case, image capture should be repeated, or the patient should be scheduled for a face-to-face ophthalmological evaluation; 2) no signs of DR or other pathologies are observed; patients are then scheduled for the next examination cycle according to regional clinical practice guidelines; and 3) presumably pathological, i.e., signs of DR and/or other pathologies are observed.

Only in the last case, a medical retina ophthalmologist performed a second reading of the images, while in the other two cases, the patient received a report through their GP and determined the necessary surveillance or the promptness with which the patient should be seen at their referral hospital.

Following the protocol described, in 2013, a pilot experiment of DR screening was conducted under the auspices of Sacyl in the diabetic population residing in a rural health area to determine the utility and cost-effectiveness of implementing this new DR screening system and to assess the extension of the program to other areas. The city chosen to conduct the analysis

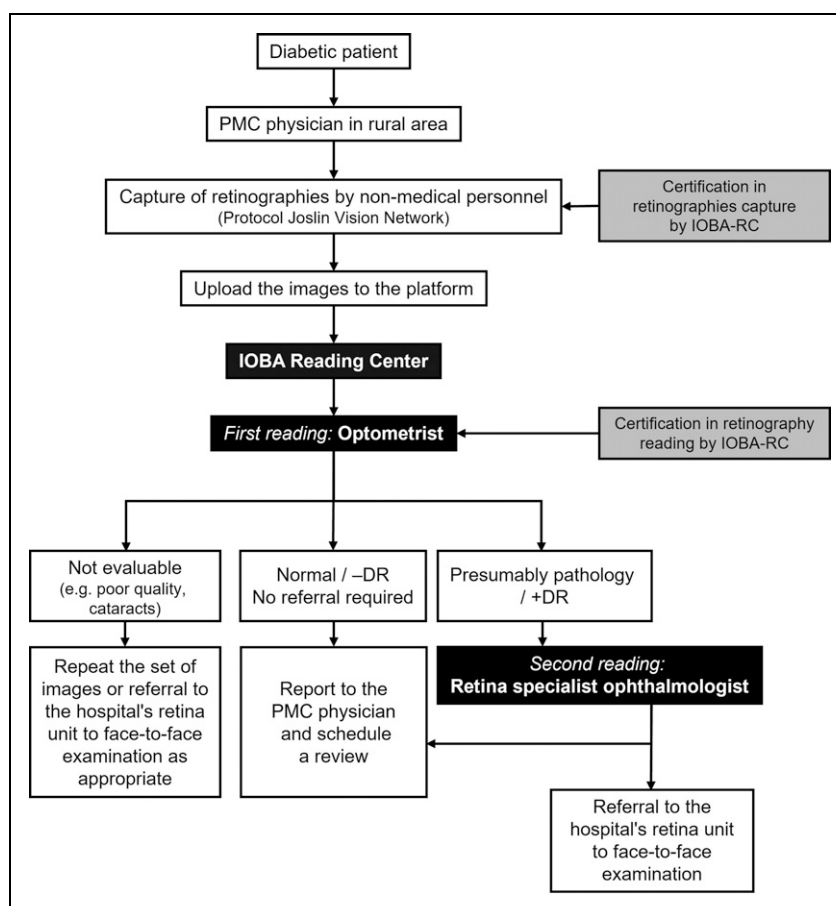


Fig. 1. Patient flowchart of the DR screening program performed by IOBA-RC. PMC, primary care center; -DR, nondiabetic retinopathy presence; +DR, diabetic retinopathy presence.

of DR screening was Medina de Rioseco (Valladolid, Castilla y León, Spain), situated approximately 40 km from Valladolid, the capital of the Castilla y León region, which lacks a general ophthalmologist.

The University of Valladolid Ethics Committee approved the study protocol. The study complied with the tenets of the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practices. Participants were informed about the study and each participant provided written consent. The inclusion criteria for participation in the program were as follows: individuals with type 1 or type 2 diabetes who had not undergone a fundus examination during the previous year, those who were not being followed by their ophthalmologist, those who can undergo adequate mydriasis, those who did not have cataracts preventing fundus visualization, and those who expressed willingness to participate.

COMPARISON OF DR TELEMEDICINE SCREENING PERFORMED BY IOBA-RC WITH TRADITIONAL MODELS

This study compared the cost-effectiveness of a pilot DR telemedicine screening program that included optometrists in

the IOBA-RC with telemedicine screening based on primary care physicians and generalist ophthalmologists and with traditional face-to-face examinations performed directly by an ophthalmologist (Fig. 3).

In the telemedicine screening process involving GPs and generalist ophthalmologists, as in other Regions of Spain, the GPs was trained in the capture and reading of retinographies and decide whether the patient was ocularly healthy or had suspicion of pathology, and it was preferable for an ophthalmologist to review the retinographies. In the latter case, the retinographies were uploaded to a technological platform and evaluated by a general ophthalmologist who decided whether the patient was ocularly healthy or they had a retinopathy not requiring additional surveillance beyond annual screenings, or if the photographic evidence was inconclusive and a face-to-face ophthalmological examination at the hospital was necessary. Finally, in the traditional face-to-face examination conducted by a specialist ophthalmologist, considered the gold-standard screening, the patient visited the referral hospital for DR screening.

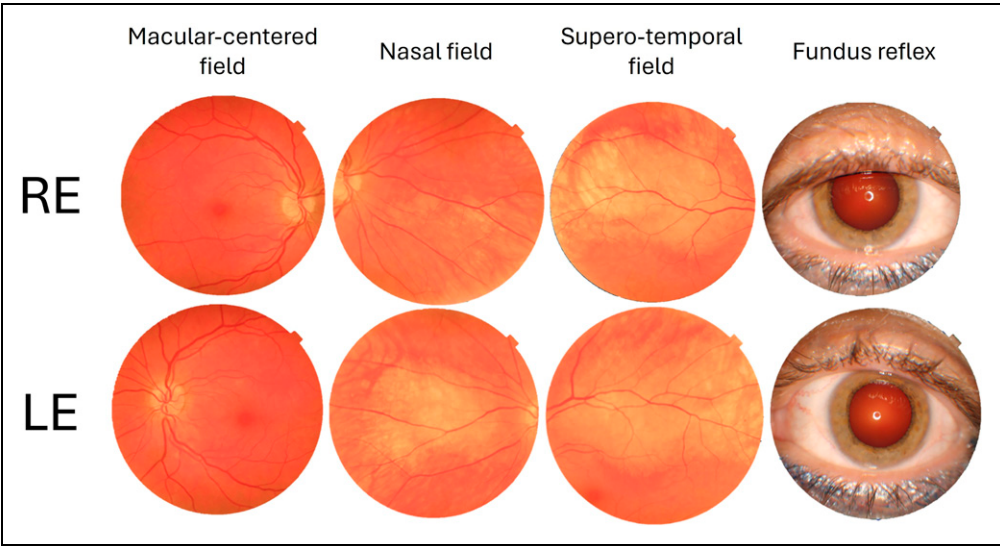


Fig. 2. The imaging protocol followed the Joslin Vision Network system,¹⁹ capturing three 45-degree images for each eye: macular-centered field (encompassing the optic disc and macula), nasal field (area of the retina nasal to the optic disc) and superotemporal field (superotemporal vascular arcade), and an image of the fundus reflex focused on the pupil. RE, right eye; LE, left eye.

Each of these procedures incurs costs associated with various medical actions at different times. In the model being evaluated, seven actions were identified. *Table 1* lists the

actions and times allocated to each used in the economic evaluation derived from the expertise of a group of GPs and ophthalmologists involved in this project. For each of these

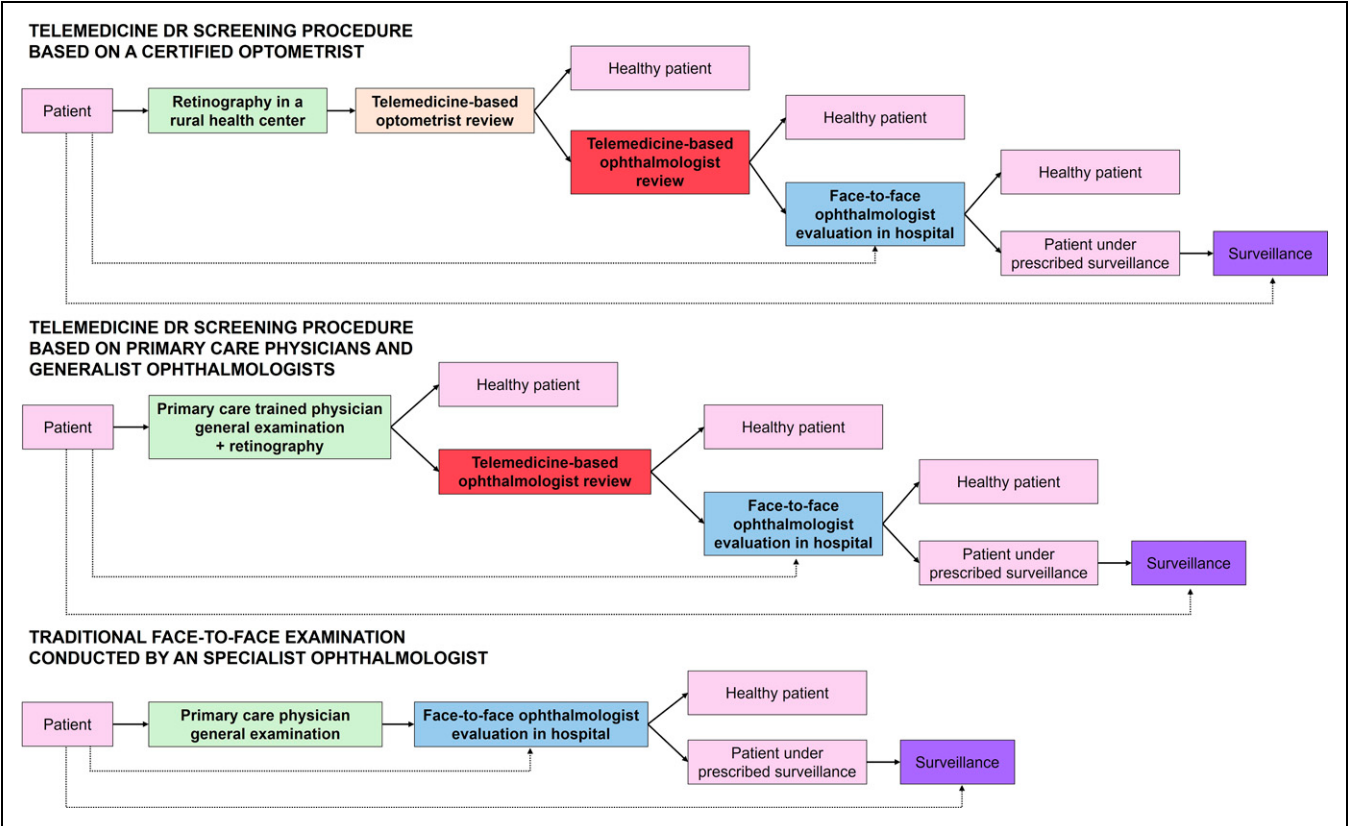


Fig. 3. Patient flowchart of the three DR screening procedures analyzed in this study in terms of cost-effectiveness. DR, diabetic retinopathy.

Table 1. Estimated Times for the Different Procedures Involved in Screening for DR			
ACTION	DESCRIPTION	PROFESSIONAL TIME (MINUTES)	PATIENT TIME (MINUTES)
1	Face-to-face assessment by a general ophthalmologist	30	180
2	Evaluation of a retinography by ophthalmologist with telemedicine	10	—
3	Performing retinographies ^a and uploading them in the technologic platform by nonmedical health personnel	20	80
4	Evaluation of a retinography set ^b by a certified optometrist	15	—
5	Face-to-face assessment in a hospital retina unit by an ophthalmologist	45	195
6	Review by primary care physician with retinographies ^a and telemedicine	30	180
7	Specific surveillance for patients with significant DR (combination of face-to-face assessment by an ophthalmologist and face-to-face assessment in the retina unit)	36	186

^aThis program uses the three fields of the Joslin Vision Network.

^bIn addition to the three images of the posterior pole, an image focused on the iris to evaluate the presence of cataracts in cases of poor image quality is added.

actions, both private costs paid by the patients and public costs covered by the public health system were considered. *Table 1* shows the cost estimates that also considered the time required to perform each action by both the patients and the involved professionals. Within the public costs, those related to personnel (ophthalmologist, GP, nurse in hospital, nurse in rural health center, and optometrist), expendable material (mydriatic drops and gauze pads), and inventoriable material (optotypes, slit-lamp, ophthalmoscope, manual tonometer, examination lenses, retinography, and digital technologic platform) were included as appropriate. The associated costs for the use of the facilities were not considered in this study.

COST-EFFECTIVENESS ANALYSIS OF THE DR SCREENING PROCEDURES

A decision tree was developed to perform a cost-effectiveness analysis of the DR telemedicine screening based on optometrists in the IOBA-RC with telemedicine screening based on GPs and generalist ophthalmologists and with traditional face-to-face examinations conducted by an ophthalmologist, encompassing all possible actions outlined in *Table 1*. The cost-effectiveness analysis was calculated using the probabilities found in the pilot study conducted by the IOBA-RC. For this study, three alternative final health states were considered: diabetic patients who do not have DR or had DR to a degree that did not necessitate treatment (–DR); patients with DR requiring treatment who were referred to undergo treatment (+DR surveillance); and patients with DR requiring treatment who due to lack of early detection had not yet been referred for appropriate treatment (+DR not surveillance).

For each of the potential states (–DR, +DR surveillance, +DR not surveillance), a quality-of-life (QoL) value ranging from 0 to 1 was assigned, with 0 representing death and 1 representing the QoL of a completely healthy individual. These QoL values were chosen arbitrarily based on previous research,²⁰ with an estimated QoL of 0.85 for a patient without DR and 0.72 for a patient with high-risk DR. Therefore, a QoL value of 0.85 was suggested for the –DR group, 0.83 for the +DR surveillance group, and 0.80 for the +DR not surveillance group. However, it is important to consider these data cautiously, in that they were proposed as an initial approximation for the assessment of this pilot experience.

In the decision tree outlined in this study, various branches led patients to a final state with a specific QoL (–DR, +DR surveillance, +DR not surveillance), each associated with screening and treatment costs, and with a certain probability of occurrence. Using this information, the cost of patient screening was estimated by adding the screening costs of each branch, weighted by their respective probabilities. The patient QoL was determined by adding the surveillance costs of each branch, weighted by their respective probabilities. Finally, the decision tree facilitated the calculation of the QoL for a patient by adding the QoL associated with each branch, weighted by its probability.

Results

In the pilot experience of the DR screening procedure, based on image reading by optometrists certified at the IOBA-RC, 289 of 443 diabetic patients were eligible for screening via teleophthalmology and agreed to participate. Of these 289 patients, 28 cases were not included because

they were not assessable for medical reasons. Of the 261 patients who underwent screening through IOBA-RC procedure, 42 had significant DR (+DR) and consequently were referred to their hospital. The remaining 219 cases did not have DR or had DR that did not require treatment (−DR). Of the 261 patients included in the study, 77 patients were selected randomly to determine diagnostic probabilities and conduct cost-effectiveness analysis. With the IOBA-RC screening program, a sensitivity of 100% and a specificity of 74.1% were found in the first reading performed only by a certified optometrist.

ANALYSIS OF ASSOCIATED COSTS IN THE DIFFERENT PROCEDURES

Table 2 shows the private, public, and total costs per patient associated with the different medical screening and surveillance procedures. To calculate these costs, the estimated times for each action described in Table 1 have been considered.

COST-EFFECTIVENESS ANALYSIS

Based on the data from the pilot study, Fig. 4 shows the resultant decision tree. The probabilities observed in the

analyzed patients of the pilot study ($n = 77$) were that 75.3% of patients did not have DR or had DR to a degree that did not necessitate treatment (−DR), while 24.7% of patients had DR and required evaluation by a retina specialist (+DR). In the first scenario, the absence of screening incurs no associated costs, but the QoL is the lowest (0.838) compared with the alternative screening procedures. The remaining procedures yielded the same QoL (0.845), with the telemedicine-based DR optometric screening program being the least expensive option. (Fig. 3, Table 3).

Discussion

The telemedicine-based optometric screening program for DR in a RC identified greater cost savings than telemedicine based on those conducted by GP and general ophthalmologists and compared with face-to-face examinations conducted by ophthalmologists in a developed country with a universal health care system. The screening model developed by the IOBA serves not only for the initial screening of the disease but also allows for the expansion of this teleophthalmology program to follow all diabetic patients and probably those with other prevalent ocular diseases. Moreover, these

Table 2. Summary of the Costs/Patient Associated with the Different Procedures Involved in DR Screening

ACTION	DESCRIPTION	PRIVATE COSTS ^a	PUBLIC COSTS				TOTAL COSTS
			Personnel ^b	Consumables ^c	Inventoriable ^d	Total	
1	Face-to-face consultation by a general ophthalmologist	€40.10	€27.60	€0.049	€0.26	€27.91	€68.01
2	Evaluation of retinography by an ophthalmologist through telemedicine	—	€5.92	—	€0.012	€5.93	€5.93
3	Realization of retinography and upload to the technologic platform of the results by nonmedical health personnel	€15.57	€6.95	€0.049	€2.67	€9.66	€25.23
4	Evaluation of retinography by a certified optometrist	—	€4.92	—	€0.019	€4.94	€4.94
5	Face-to-face evaluation in a hospital retina unit by an ophthalmologist	€42.63	€41.40	€0.049	€0.39	€41.84	€84.47
6	Specific surveillance for patients with significant diabetic retinopathy (combination of face-to-face assessment by a general ophthalmologist and face-to-face assessment in the retina unit)	€41.14	€33.26	€0.049	€0.31	€33.62	€74.76

^aTotal time encompassing travel to their reference hospital located in Valladolid or the primary care center in Medina de Rioseco, waiting time, and face-to-face consultation were considered (patient and companion). Regarding transport costs, the round-trip distance of 80 km (40 km each way) from their homes in the rural area of Medina de Rioseco to the hospital in Valladolid was estimated. Similarly, for those traveling to the primary care center in Medina de Rioseco, a total round-trip distance of 30 km (15 km each way) was estimated.

^bFive types of professionals were included: hospital specialist (ophthalmologist; €59,100), general physician in rural health center (€63,100), nurse in hospital (€32,800), nurse in rural health center (€34,700), and optometrist (€32,000).

^cMydriatic drops and gauze.

^dFace-to-face examination by the ophthalmologist: optotypes, slit lamp, ophthalmoscope, manual tonometer and examination lenses. Telemedicine programs: optotypes, fundus camera, technologic platform and laptop with internet connection and software licenses.

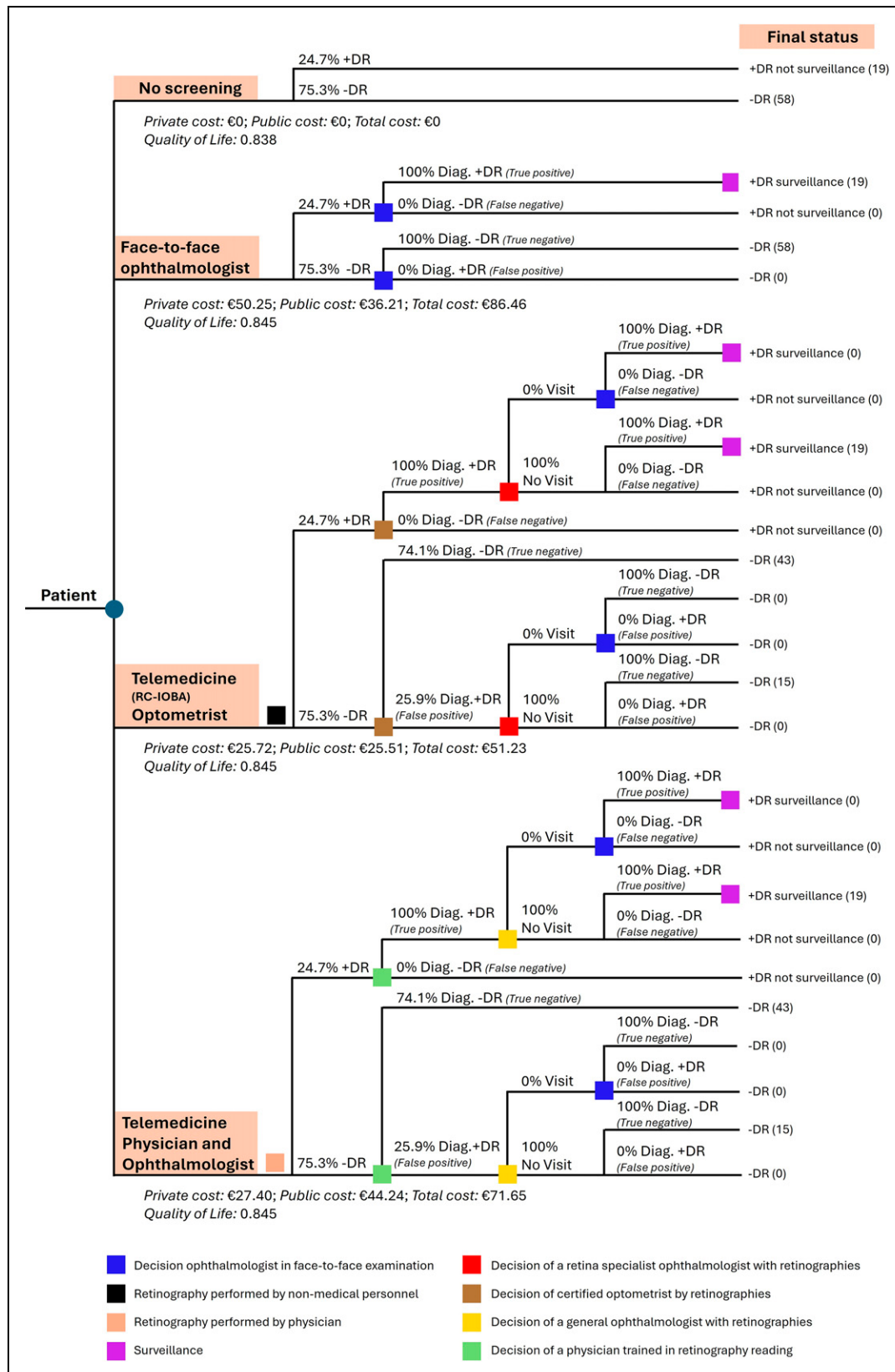


Fig. 4. Decision tree with the comparison of the three DR screening procedures using the probabilities of the pilot project of IOBA-RC. Legend: +DR, DR with need for additional surveillance; -DR: good ocular health or DR not requiring additional surveillance; Visit, a face-to-face visit with the ophthalmologist is required; No-Visit, a face-to-face visit with the ophthalmologist is not required.

Table 3. Costs (€/Patient) and Quality of Life of the Different Diabetic Retinopathy Screening Alternatives

	TOTAL COST	PRIVATE COST	PUBLIC COST	QUALITY OF LIFE
No screening	0	0	0	0.838
Telemedicine based on certified optometrist	€51.23	€25.72	€25.51	0.845
Telemedicine based on primary care physician and general ophthalmologist	€71.65	€27.40	€44.24	0.845
Face-to-face examination by the ophthalmologist	€86.46	€50.25	€36.21	0.845

results highlighted the advantage of RC that enable the outsourcing of procedures and eliminates the dependency on a physical location to provide optimal patient care services.

Early detection of DR through telemedicine, a practical approach to prevent vision loss, is widely accepted.¹¹ In 2020,¹⁰ Avidor et al. published a review on screening publications performed between 2010 and 2020 that included 2,238 studies, of which only seven included economic information. Among these, only four were performed in developed countries. Their conclusion was that telemedicine for screening DR offers significant cost savings, particularly in low-income populations and patients from rural areas.

However, as mentioned previously, the cost-effectiveness may differ in some European countries with generalized public health systems offering, at least in theory, universal coverage. In those cases, the creation of a network of peripheral centers for DR screening entails increased equipment and personnel costs, which must be carefully evaluated. Moreover, as mentioned, we are now also trying to incorporate age-related macular degeneration (AMD) screening by telemedicine, which gives more value to the network.²¹

The main novelty of this study is the implementation of a DR screening model that incorporates a certified optometrist within a RC, who performs the initial reading of the images. In Spain, DR screening usually is carried out by GPs or endocrinologists as the first readers, with the support of ophthalmologists through telemedicine.²² The current study showed that the screening model that includes an optometrist is the most cost-effective for the public health system. It is also important to highlight that the first reading performed by a certified optometrist in this screening model achieved a sensitivity of 100%, which is comparable to the sensitivity of ophthalmologists in face-to-face examinations. However, the specificity was 74.1%, which was relatively low but clearly explainable in that the optometrist refers any patient with suspected DR, even mild disease, for a second reading as well as other retinal pathologies. Some other programs based on GPs reported impressive results, such as a sensibility of 89.69%, specificity 92.3%, and accuracy 84.51%;²³ however, in this case, human medical resources were being used that could have other more complex functions.

By the end of 2017, the Regional Government of Castilla y León started a telemedicine screening program that currently covers four provinces of the autonomous region and has served 35,000 patients.²⁴ Before implementing it, a cost-effectiveness study was conducted, which is the focus of the present work, and we believe it remains relevant, as similar studies have not been identified in the reviewed literature. In fact, in Spain, only one publication provided efficacy data, but no information on economic aspects was reported.²² Only two similar projects have been carried out in other European countries but they also did not provide cost-effectiveness information.^{25,26} Currently, the platform remains operational, and to date, over 35,000 diabetic patients have been screened by IOBA-RC, which conducts DR screening in four rural and five urban health areas in the autonomous community of Castilla y León. According to our records, only 1.3% of these diabetic patients have required an in-person referral to the hospital for specific surveillance of their DR by retinal specialists. This has resulted in time savings for both patients and the public health system. It also has helped to overcome accessibility challenges faced by many diabetic patients in urban and rural areas, in that they do not need to travel to the referral hospital for DR screening. This referral rate found over the years at IOBA-RC through its screening program is similar to that reported by the Andalusian telemedicine program, in which GPs or endocrinologists are responsible for the initial interpretation of retinographies.²² Between 2005 and 2019, 44,815 diabetic patients in the Andalusian telemedicine program had some degree of DR, and 1.5% required referral to the hospital due to forms of DR that necessitated specific surveillance.²²

A limitation of this work was the time elapsed since it was carried out until now, where the actual costs may have changed. In fact, the value of €100 in 2013 is equivalent to €121 in 2023 with the cumulative inflation rate reaching 21.5% and a Consumer Price Index value of 122.3.²⁷ However, we believe that, in relative terms, the study still holds value and was worth publishing. Due to the screening program's reliance on retinography and the capture of retinal

images, only ophthalmic conditions and emergencies affecting the posterior pole of the eye could be detected. Therefore, ophthalmic issues involving the anterior pole or ocular surface are not evaluated. In addition, some DR diagnoses might also have been overlooked if diabetic patients declined to participate in the program. This could affect the prevalence rate of the disease. In addition to DR, this screening system allows evaluation of other diseases affecting the posterior pole, such as AMD. Efforts are underway to expand the platform to include screening for AMD within the public health care system.

To extrapolate the results obtained from this pilot study to the entire population of the Autonomous Region of Castilla y León, the costs per patient for both alternatives for screening for DR were multiplied by the entire diabetic population. To reach this estimate, it was assumed that approximately 8% of the population of Castilla y León had diabetes and that 50% of them might undergo a screening process, based on the total number of screened patients of about 100,000. Based on these data, the option of optometric screening would involve a cost of €5.1 million. If the IOBA-RC model is compared with the telemedicine screening model based on GPs as the first readers, the total costs would increase by 39.8% in the latter. However, in the gold-standard traditional model of face-to-face assessment by the ophthalmologist, the total cost of DR screening would increase by 68.8%.

The use of telemedicine for DR screening has previously been shown to be more cost-effective than traditional examination by an ophthalmologist.^{28–31} Kanjee et al.³¹ reported a lower cost for the teleophthalmology program compared with conventional face-to-face screening in a Canadian cohort. Cost-effectiveness calculations showed that the teleophthalmology program, in which trained nurses went to Canadian localities and obtained photographs, was more cost-effective compared with the traditional screening model. The telemedicine program cost \$489,867 annually, whereas the traditional face-to-face screening model cost \$1,781,620 annually.³¹ This is interesting experience in that the Canadian health care system shares many similarities with European ones.³²

Therefore, we concluded that the use of teleophthalmology with the involvement of optometrists in a RC is cost saving. The use of telemedicine can reduce costs and enable accurate early detection of DR, thereby slowing disease progression and preventing severe vision loss in diabetic patients. However, the interpretation of images and the detection of fundus lesions in current DR telemedicine programs is a manual process, which can be time-consuming for professionals and may vary between observers.^{33,34}

The diabetic population is projected to grow in the coming years, leading to increased resource consumption. To address

this challenge, software manufacturers have developed artificial intelligence (AI) systems for the detection and classification of DR. Future research in AI is crucial for addressing potential challenges and improving the implementation of these technologies within health care screening programs. However, these AI programs are challenged by a lack of legal regulations on decision-making accountability.³⁵

Conclusions

The telemedicine-based optometric screening program for DR in a RC showed cost savings even in a developed country with a universal health care system. The IOBA-RC program has shown better economic results than telemedicine based on GPs' and general ophthalmologists' evaluations and compared with face-to-face examinations conducted by ophthalmologists. In addition, this DR screening system showed the same sensitivity as traditional face-to-face screening. These results strongly support the expansion of this teleophthalmology program not only for screening but also for the follow-up of diabetes patients. These findings should be considered by health authorities within public health systems.

Availability of Data and Materials

All related data were displayed in the article. Further information regarding the data can be obtained by contacting the corresponding authors.

Authors' Contributions

All authors were involved in the conception, design, and conduct of the study and the analysis and interpretation of the results. All authors wrote the first draft of the article, and all authors edited, reviewed, and approved the final version of the article.

Disclosure Statement

No competing financial interests exist.

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