ORIGINAL PAPER

Design, Development, and Evaluation of a Teleophthalmology System Using a Low-Cost Fundus Camera

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ABSTRACT

Introduction: The increasing prevalence of diabetic retinopathy in developing countries has become a worldwide concern. This problem is preventable by timely diagnosis and treatment; however, in the majority of cases, patients attend the eye clinics very late because of a lack of specialists and travel difficulties. Running a teleophthalmology system would significantly help to manage this disease. **Aim:** This study seeks to assess the accuracy of the teleophthalmology system and its effect on reducing unnecessary referrals in Iran. **Methods:** This study was conducted on 125 diabetic patients. First, the patients were examined by a retina specialist using a slit lamp and, then, single-field digital photos were captured by a portable, low-cost fundus camera. The images were uploaded onto a website and, after two months, were assessed by two retina specialists and two general practitioners (GPs). Finally, the diagnoses based on the digital photos were contrasted with the diagnoses established through face-to-face visits as a gold standard. **Results:** Out of 125 diabetic patients, eight (6.4%) were removed because of low-quality images and a total of 117 were evaluated. The sensitivity and specificity of each retina specialist presented with the photographs produced success rates of 90% and 97% respectively when judged against the gold standard of face-to-face visits. The rates of sensitivity for retinopathy referrals from the retina specialists were 92% and 85%. The sensitivity and specificity of their diagnoses of clinically significant macular edema (CSME) were calculated at 93% and 100%. The rates of sensitivity for each GP were 95% and 93% and the level of specificity was estimated to be approximately 98% for both GPs. The diagnosis rate for GPs when viewing the photographs as opposed to hosting face-to-face visits was more than 90%. Generally, with the implementation of this system, between 40% and 55% of referrals were calculated to have been avoidable. **Conclusion:** Our results from the first-ever research conducted on this topic in Iran showed that the teleophthalmology system is extremely accurate, that it can prevent unnecessary referrals and that it is useful for locating treatable patients. The results of this study could be of assistance in the running and expansion of such systems throughout Iran and Kerman Province to reduce eye damage arising from diabetes, decrease avoidable referrals to clinics, increase the availability of specialist visits for people in remote and rural areas and optimize the use of clinical infrastructures for patients in emergencies.

Keywords: telemedicine, teleophthalmology, diabetic retinopathy, developing countries.

1. INTRODUCTION

Diabetes is a prevalent global disease. In 2015, the number of people with this disease was estimated to be 415 million - 75% of whom were living in low- and middle-income countries - and this number is anticipated to increase to 642 million by 2040 (1). This issue poses a heavy burden on healthcare systems as a result of the complications arising from the disease. According to the World Health Organization (WHO) (2), the prevalence of this disease in Iran is 10.3% (affecting more than 7 million people). The most common ocular complication of diabetes is diabetic retinopathy (DR), which is one of the main causes of blindness in adults between 20 and 74 years old (3). Approximately 35% of

people affected by diabetes around the world have some degree of DR (4). Throughout Iran, the prevalence of this complication is 29.6% in Yazd, 37% in Tehran and 45.1% in Kerman Province (5-7). Early diagnosis and timely treatment can reduce the resulting visual impairments by up to 98% (8). For this reason, it is recommended that diabetic patients visit an ophthalmologist at least once a year to reduce the severity and incidence of DR (9). However, more than 50% of patients (10) do not refer for various reasons, such as difficult access to health centers (10) and a shortage of specialists (11).

The results of the Resnikov study showed that despite the presence of more than 200,000 ophthalmologists worldwide, shortages of ophthalmologists are remarkably high in developing countries (12). Kerman is one of the southern provinces of Iran, with a population of 738,724 in its capital, Kerman City, and 2,425,994 across its other counties (13). As 75% of the Kerman population inhabits parts of the province outside the capital and there are currently only four retina specialists in the province—all working in the province capital—patients must travel to Kerman City for the regular monitoring of ocular complications arising from diabetes. In addition to difficulties with travel and costs, large numbers of patients, along with shortages of specialists, increase patients' waiting time during visits and cause delays in the timely receipt of health care services. Therefore, the design and implementation of a system for the early diagnosis and referral of patients with emergency conditions would be an effective step in managing this complication and would mitigate the costs to the community incurred by visual impairment, such as patient disabilities. One of the known solutions to such problems around the world is teleophthalmology, an effective strategy

for early diagnosis and treatment. Tele ophthalmology improves access to healthcare services, especially in remote areas, increases the rates of timely examinations(14), saves time and reduces unnecessary referrals (15). Several teleophthalmology projects have been implemented so far, providing benefits such as accuracy and reliability (16), cost-effectiveness (14), and efficiency (17). Also, studies have shown that teleophthalmology, through increasing collaboration between general practitioners and specialists, is an appropriate method for reducing the burden on specialists and increasing the speed of service delivery to patients (18, 19).

To this end, GPs make diagnoses during initial assessments, identifying patients who can be treated and referring them to the specialists. However, despite the proven effectiveness of the teleophthalmology system, no studies have previously been undertaken in Iran on this issue. As a result of differences in infrastructure, facilities and human and cultural factors distinguishing the current study from similar foreign research, this study utilized a web-based teleophthalmology system using a cheap fundus camera to answer two main questions:

- Is the diagnostic accuracy of this system acceptable concerning the standard of face-to-face visits (the golden standard)?
- Do general practitioners have the ability to prevent unnecessary referrals to specialists?

2. AIM

This study seeks to assess the accuracy of the teleophthalmology system and its effect on reducing unnecessary referrals in Iran..

3. METHODS

Study Design and Participants

This cross-sectional study was conducted on 125 diabetic patients who had been referred to Shafa Hospital (the only government-run ophthalmology center in Kerman City) and Basir Subspecialty

Ophthalmology Clinic (one of the main centers to which diabetic patients are referred) in Kerman in 2017. Age-related macular degeneration, severe cataracts, vitreous hemorrhage, previous vitreoretinal surgery and physical or mental disabilities preventing patient collaboration were the exclusion criteria.

Procedure

Examinations were performed in two ways: conventional (face-to-face) meetings and digital (virtual) assessments. After the completion of the face-to-face examinations, two months elapsed before the digital imaging assessments were conducted.

Face-to-Face Examinations (the Gold Standard)

First, the visual acuity of the patient was measured using a Snell chart at the standard distances of four and six meters. Then, the pupil was dilated using a drop of Tropicamide (1%) and a face-to-face examination was conducted by Retina Specialist 1 (S1) using a Topcon slit lamp and a Volk 90 Diopter Lens. Each patient's best-corrected visual acuity was recorded, along with the patient's identity number, age, gender, place of residence and the physician's diagnosis during the face-to-face examination. As all retina specialists were located in the capital of the province, places of residence was categorized as either 'the center' or 'other parts' of the province.

Virtual Examinations (Digital Imaging)

The photographer was a senior postgraduate student of medical informatics who had acquired the skill of retina imaging through a three-week training course run by S1 and was practicing on volunteer patients. Because of the small sizes of the patients' pupils and their mild cataracts, digital imaging was performed using a 1920*1080-pixel resolution non-mydriatic Horus scope camera immediately after the face-to-face examination while the pupils were still dilated. After explaining the purpose of the study and obtaining verbal consent, the photographer took a single-field image centered on the macula and showing the optic nerve and superior and inferior vascular arcades of the patient; if the image quality was not acceptable, the imaging process was repeated. An interval of two months was preserved following the face-to-face examinations before the virtual assessments were conducted to ensure that S1 did not remember the diagnoses(20).

Web Design

The store-and-forward teleophthalmology system was designed and implemented using PHP server-side programming language. HTML, CSS, and JavaScript were utilized to implement the front end and MySQL was applied to design the database. The images were stored in JPEG format and, along with other patient information, were accessible via the domain website www.teleeye.ir)for six months(using a username and password.

Interpreting Images

Two retina specialists (S1, S2) and two general practitioners (G1, G2) analyzed the digital images. According to the doctors' instructions, the stored images were classified into two groups: interpretable and uninterpretable. Images of poor quality or those taken from an incorrect location were considered uninterpretable and excluded from the analysis and were added to the referral cases.

Retina Specialists

The interpretable images were independently reviewed by the two retina specialists for the presence of DR and CSME. DR was categorized according to the recommendations of the Early Treatment of Diabetes Retinopathy Study (ETDRS) as follows:

- Normal,
- Non-proliferative diabetic retinopathy (NPDR),
- Proliferative diabetic retinopathy (PDR),
- High-risk proliferative diabetic retinopathy (HPDR),
- Advanced proliferative diabetic retinopathy (APDR).

Further, the criteria for patient referral based on the specialists' opinions were as follows:

Group 1 (non-referral): In normal patients after 12 months and patients diagnosed with NPDR exhibiting no problems in the macula area, the retina imaging should be repeated after three to six months.

Group 2 (referral): The ETDRS referral threshold was defined as the presence of either ETDRS level ≥ 61 (APDR–HPDR–PDR) or CSME—each of which required that the patient be referred to a specialist within one month to receive medical treatment.

General Practitioners

As a consequence of the inability of GPs to differentiate different types of DR, the GPs categorized the images simply as either normal (non-referral) or abnormal (referral). Finally, the results of the digital retinal imaging were compared with those from the face-to-face examinations as the gold standard.

Data Analysis

Data analysis was conducted using SPSS Software Version 25. To evaluate the diagnoses produced from the digital images in contrast to those established during face-to-face visits, the Kappa agreement coefficient, sensitivity, and specificity were calculated. Chi-Square was used to ascertain the relationship between the place of residence and the referral group. A generalized estimating equation (GEE) analysis was used to check the significance of diagnostic differences between specialists. Ethics The study was approved by the Research Ethics Committee of Kerman University of Medical Sciences (Code of Ethics: 95000408). Informed consent was obtained from all patients included in the study and was assured about the confidentiality of their information.

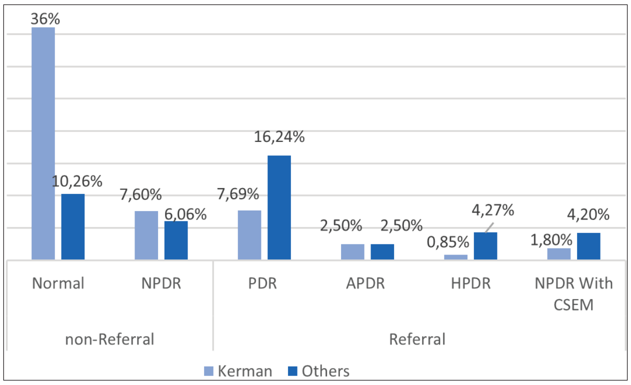
4. RESULTS

Sample Characteristics

In the present study, retinal imaging was carried out for 125 diabetic patients, eight of whom were excluded as a result of the poor quality of their images. Finally, 117 diabetic patients, 79 women (67.5%) and 38 men (32.5%), with a mean age of 56.7 ± 9.3 years (24–86 years old) were investigated.

Face-to-Face Examinations

Of the face-to-face examinations conducted with the slit lamp, 54 (46.2%) were normal and 63 (53.8%) resulted in a diagnosis of DR or "CSME with DR" —comprising 16 (13.6%) NPDR, 26 (22.2%) PDR, 3(2.6%) APDR, 3 (2.6%) HPDR and 15 (12.8%) CSME; of these, 6% had CSME with NPDR and 6.8% had CSME with referral retinopathy (PDR, HPDR and APDR). The highest rate of DR (69.8%) was observed in the age group spanning 41 to 60 years. More than half of the normal cases scheduled for annual visits were female (65%) and more than two-thirds of them lived in Kerman City. Referral cases (CSME with NPDR, PDR, HPDR, and APDR) and place of residence had a significant relationship (p = 0.00), that is, 68% of the referral cases did not live in the capital of the province and were residents of other counties (Graph 1).



Graph 1. Frequency of Type of DR and CSME Based on Place of Residence

Digital Imaging

On the whole, eight images (6.4%) were not of acceptable quality and were excluded from the analysis but were added to the referral cases.

Retina Specialists

The sensitivity and specificity of S1 in the diagnosis of different types of retinopathy when presented with photographs, as opposed to during face-to-face exams, were 92% and 96% respectively; for S2, they were 88% and 98% respectively. Similarly, the sensitivity of the diagnoses of referral retinopathy (PDR, HPDR, and

APDR) was 0.92% for S1 and 0.85% for S2. Out of the 15 patients with CSME diagnoses, one case was not diagnosed by either retina specialist; therefore, the sensitivity and the specificity of the diagnoses of CSME were 93% and 100% respectively for both specialists. The positive predictive value (PPV) and the negative predictive value (NPV) for S1 were 95% and 96% respectively; for S2, they were 90% and 98% respectively. The Kappa agreement coefficient between the methods of face-to-face and digital assessment conducted by S1 was 0.94; for the diagnoses produced by S2, it was 0.91. Diagnosis accuracy was estimated at 98% and 97% for S1 and S2 respectively. On the whole, only about 50.4% of patients needed a face-to-face visit from the retinal specialists (44% for the presence of retinopathy and 6.4% as a result of uninterpretable images). A significant difference was not observed between the diagnoses of the retinal specialists and the likelihood of diagnosis by both was more than 90%.

General Practitioners

The ability of the GPs to identify either normal or referral cases was evaluated concerning the diagnoses of S1 during face-to-face exams (the gold standard). The sensitivities of the diagnoses of G1 and G2 were 95% and 93% respectively and the specificity of each was 98%. The Kappa index for the diagnoses by G1 and G2, when compared with the face-to-face exams, was, respectively, 0.93 and 0.91; considering the different evaluations by GPs and retina specialists, the Kappa index was calculated as 0.88 to 0.91. The PPV for both G1 and G2 was 98% and the NPV was 94% for G1 and 92% for G2. On the whole, the rates of referral were 58.5% by G1 (52.1% for the presence of retinopathy and 6.4% as a result of uninterpretable images) and 57.7% by G2 (51.3% for retinopathy and 6.4% as a consequence of uninterpretable images).

5. DISCUSSION

Most patients with retinopathy are referred to specialists in its advanced stages during which treatment is difficult. Early diagnosis and timely treatment are very effective in the prevention of blindness and in decreasing the related costs imposed on the health system. The present study marked our first experience of the implementation of the teleophthalmology project in Iran to evaluate its diagnostic accuracy. The results showed that teleophthalmology is a highly accurate method for identifying patients—especially treatable cases—and that it is very efficient in decreasing unnecessary referrals. The use of teleophthalmology programs as opposed to ETDRS as a standard for the diagnosis of DR has been accepted, but it nonetheless requires a photographer with adequate skills and it is very timely and costly. We used face-to-face examination with a slit lamp as our golden standard, since it is desirable in contrast to the ETDRS (21). The British Diabetic Association (BDA) has recommended a minimum sensitivity of 80% and minimum specificity of 95% against the golden standard as the criteria for a method to be acceptable for the digital diagnosis of retinopathy (22). In the present study, the sensitivity and specificity of the diagnoses of different types of retinopathy by retina specialists were defined according to these criteria. The sensitivity of diagnoses when identifying referral cases of retinopathy was more than 80% for both specialists. This finding is also in agreement with a report by the American Academy of Ophthalmology, which reveals the efficiency of the single-field method for identifying patients who need to be referred for treatment (23). As in the present study, in a study by Landers, the diagnostic accuracy of digital single-field mydriatic images was calculated in contrast to the accuracy of slit lamp diagnoses. The sensitivity and specificity of the diagnoses of different types of retinopathy were reported as 74% and 92% respectively and for vision-threatening retinopathy, they were 86% and 95% respectively (24). The results of the above-mentioned study confirm our claim that the single-field method has acceptable diagnostic accuracy for identifying referral cases. In another study carried out intending to evaluate single-field non-mydriatic imaging in contrast to slit lamp identification, the sensitivity and specificity of retina specialists' diagnoses were 53.8% and 89% respectively and the researchers claimed that single-field non-mydriatic imaging did not have adequate accuracy for the diagnosis of DR (25). The difference between this finding and the results of the present study could be attributed to the pupils' mydriasis and the exclusion of poor-quality images from the analysis of the current study. Murgatroyd also reported sensitivity and specificity levels of 81% and 92% respectively for single-field mydriatic imaging and 83% and 93% for three-field mydriatic imaging as opposed to face-to-face examinations (26). In Murgatroyd's study, the number of imaging fields did not affect diagnostic accuracy. This finding implies that single-field imaging in our study would likewise have had no negative effect on diagnostic accuracy. One of our goals was to investigate the levels of agreement between GPs and specialists in their diagnoses of this complication, which was calculated to be between 0.88 and 0.91, which is similar to other studies reporting levels of 0.80 to 0.95 (27, 28). The present study showed the efficiency of GPs in decreasing unnecessary referral cases in that they identified approximately 40% of cases as unnecessary for a referral. In a study by Rios, through primary evaluation by general practitioners between 55% to 68% of unnecessary referrals rate were decreased (29). In general, to manage this complication and to decrease the workload of specialists, primary evaluation by GPs and the referral of only abnormal cases to specialists are suggested. Since the estimation of the prevalence rate was not among the aims of our research and sampling was conducted in a referral center for diabetic patients, the rate of unnecessary referrals was low in the current study. More than two-thirds of the diabetic patients without DR referred for annual exams were residents of the capital of Kerman province. Conversely, the frequency of visits by patients with more severe degrees of retinopathy was higher for patients who lived in places far from the capital. This shows that limited access to specialists and transfer problems for patients could be reasons for late referrals. A study by Lee, which aimed to evaluate factors relating to the following of clinical guidance during eye exams by diabetic patients, confirmed the results of the present study—that is, diabetic patients living far away from eye care centers were referred less for routine eye exams(10). Unlike our study, research by Chin reported that, despite having more access to health centers, diabetic patients living in urban areas followed guidelines less commonly and showed higher rates of retinopathy (30). One important issue in the implementation of teleophthalmology is the number of uninterpretable images that cause an increase in referral rates. The Murgatroyd study showed that this problem could be decreased from 26% to 5% by pupil dilatation (26). The mydriasis of pupils by Tropicamide drops is a safe procedure, even in patients with chronic glaucoma (31); however, it must be conducted by a trained person, such as a GP, to prevent pupil mydriasis in patients with closed-angle glaucoma. To decrease the rate of uninterpretable images, we also performed retina imaging after pupil mydriasis. In the UK, as screening is carried out under mydriasis, a rate of less than a 5% rate of uninterpretable images is recommended (32). In the current study, most images had the adequate quality for evaluation and the rate of uninterpretable images was 6.4% (eight eyes). Another study with a similar rate (7%) was conducted by Rios (29). Another important issue is the transfer of medical images in the standard format of JPEG 2000. Our applied camera supported only jpeg format however, the study shows that jpeg format is acceptable for DR diagnosis(33). In the present study, patients found focusing on a fixed target during imaging difficult and this resulted in the lengthening of the imaging time as well as inpatient tiredness and lack of satisfaction. Therefore, we selected single-field imaging centered on the macula to identify the referral cases. Since there were no cases of NPDR among our referral cases, we were not required to evaluate it using the three categories of mild, moderate and severe. Although these classifications did not have negative effects on the process of referrals, they increased the sensitivity of our study. In future studies, it is recommended that, along with visual acuity and retina images, a pinhole for determining refractive errors and a red reflex for determining the presence of cataracts be used so that the cause of vision loss can be recognized and decision-making on referrals can be facilitated. Given the prevalence of diabetes and consequent DR, the demand for healthcare services has increased. Since an equal distribution of specialists around the country is not possible, the implementation of teleophthalmology systems seems to be necessary; therefore, governmental policy and the collaboration of insurance organizations are required to resolve legal issues and to pay for the return of service providers to increase their motivation and to prevent further costs to the health system.

6. CONCLUSION

The results of this pioneering research in Iran showed that the teleophthalmology system is accurate and capable of preventing unnecessary referrals and of identifying treatable cases. Given the shortage of specialists and increasing numbers of patients, teleophthalmology can efficiently manage this complication, prevent blindness and decreased costs to the health system. However, its implementation throughout the country requires legal infrastructure, the provision of necessary licenses, personnel training (especially for photographers) and the cooperation of physicians. The results of this study can be used for the implementation and development of this system in Iran for the early diagnosis of treatable patients, the reduction of unnecessary referrals to health centers and the optimum use of medical resources for patients with serious conditions.

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