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Telehealth Program for Diabetic Retinopathy in Rural South India: A Pilot Study

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Abstract

This study was done to evaluate the efficacy of telehealth programme for diabetic retinopathy and estimate the grading-agreement between digital fundus photography and indirect Ophthalmoscopy observations. The data were obtained from 511 diabetics examined at the six screening camps organized in rural south India. Topcon TRC NW 100 non-mydriatic camera was used to get digital single 450 fundus photographs (with dilated pupil) centered midway between the center of the macula and the disc. A retinal specialist in the base hospital evaluated the images.. Patients with sight threatening diabetic retinopathy were re-examined in the base hospital, and their fundus findings based on indirect ophthalmoscopy were compared with those obtained by digital fundus photography. Of the 1013 images, 22 (2.2%) could not be graded due to poor image quality. Of the remaining 991 images, the fundus was graded normal in 802 and abnormal with evidence of any diabetic retinopathy in 189 (19.1%). Of the 189 eyes with diabetic retinopathy, non-proliferative DR was evident in 159 (84.1%), proliferative DR in 30 (15.9%); macular edema was evident in 52 (27.5%) eyes. The grading-agreement of DR between digital photograph and indirect ophthalmoscope was good for any retinopathy versus no retinopathy (kappa value=0.79, 95%CI: 0.68-0.88). Similarly, grading-agreement between sight-threatening DR and no sight-threatening DR, as determined by ICC, was 0.76 (95% CI, 0.63-0.85).Telehealth programme is an effective tool of early detection of sight threatening complications of diabetic retinopathy. Its use can be extended for mass screening of patients in rural settings where availability of health care professionals is inadequate.

Introduction

The World Health Organization (WHO) has cautioned of the upcoming epidemic of diabetes mellitus all over the world in two decades. The projected increase in diabetic rate in India will be alarmingly high -150% as compared to 42% elsewhere.[1] Despite the availability of photocoagulation and vitreous surgery for the past 3-4 decades, diabetic retinopathy remains one of the leading causes of blindness among the working-age population. There is better understanding now of the importance of early diagnosis and prompt treatment of diabetic retinopathy. Yet, an estimated one-half of the diabetic population does not receive annual dilated eye examination.[2] Treating end-stage diabetic retinopathy does not provide desirable visual results and is typically frustrating for the patient as well as the ophthalmologist. Late-stage treatment is also enormously expensive.[3]

One of the challenges of diabetic retinopathy screening, particularly in India, is to make these measures available in rural areas where health care resources are limited. To compound the problem, nearly 70% of the population lives in rural areas where 70% of ophthalmologists live in urban areas.[4] The ophthalmologist/population ratio is 1:107,000 in rural areas.[5] Use of teleophthalmology to screen diabetic retinopathy has been recommended in the recent past.[6] Yet, its effectiveness has not been evaluated in rural India. This paper describes the methodology and results of such screening using single field 450 digital fundus images transmitted via satellite to the base hospital for photograph reading and counseling. Patients who visited the base hospital for further investigation, such as fluorescein angiography, were compared for diabetic retinopathy grading-agreement with those obtained with indirect ophthalmoscopy.

Materials and Methods

Between August and October 2004, six diabetic retinopathy-screening camps were conducted in the Southern rural areas of India. These camps were organized in six villages of Tamil Nadu; which were located at an average distance of 198 Km (range, 148-229 km) from the base hospital.

A customized mobile van with in-built ophthalmic examination facility having satellite connectivity (courtesy of the Indian Space Research Organization) along with a social worker and an optometrist visited the selected sites. In each camp, 80-100 diabetic patients about the age of 30 years were examined. Study data sheet included age, gender, duration of diabetes, details of first and last eye examination and any treatment received for diabetic retinopathy.

Visual acuity was measured using log-MAR chart. Anterior segment was evaluated with hand-held (Heines HSL 100 CE) slit-lamp, and measurement of intraocular pressure was performed with Schiotz tonometer. After pupillary dilatation, a single 450 digital fundus photograph centered midway between the center of the macula and the disc was taken with Topcon TRC NW 100 non-mydriatic camera (Topcon, Tokyo, Japan). The images were converted to DICOM (Digital Imaging and Communications in Medicine) format by telemedicine software, PACS (Picture archival and communication software, Vipro InfoTech, Germany). These images were transferred to the base hospital, a tertiary eye care hospital at Chennai, Tamil Nadu by a satellite link using VSAT (Very small aperture terminal) hardware. The transmission rate was 384 kilobytes per second (kbps). All images were examined by a retinal specialist in real-time using video-conferencing system (Sony, Tokyo, Japan). The patient (who was in the mobile van) was then advised on the diagnosis, treatment, and follow-up.

Diabetic retinopathy was graded as per the new disease severity scale recommended by the American Academy of Ophthalmology.[7] Sight threatening diabetic retinopathy was defined as those eyes that had proliferative diabetic retinopathy or severe diabetic macular edema or a combination of both. These patients were re-examined in the base hospital, and this provided an excellent opportunity to compare their original diabetic retinopathy grading as assessed with digital photography with that assessed by indirect ophthalmoscopy. Diabetic retinopathy grading-agreement was analyzed using unweighted kappa value for categorical data, where kappa value = 0 defined no correlation and kappa value = 1 defined total correlation. The interclass coefficient correlation (ICC) was used to determine the level of agreement on stage of Diabetic Retinopathy.[8] A kappa value of ICC more than 0.7 indicated a good DR grading-agreement between two assessment techniques: real-time digital photograph reading and indirect ophthalmoscopy evaluation.

Results

The sample consisted of 511 diabetics with mean age 53.8 ±10.6 years (range 30 years –84 years), and 5.8 years (range, 1week to 35years; median, 4 years) of mean duration of diabetes underwent screening. Male to female ratio was 1.85:1. As many as 376 (73.6%) of the entire sample had never undergone an eye examination before. Of the 1022 eyes of 511 patients, in nine, digital fundus photographs were not taken because of total white cataract (6 eyes), leucomatous corneal opacity (1 eye), empty socket (1 eye), and acute angle closure glaucoma (1 eye). Patients with total cataract and acute angle closure glaucoma received appropriate treatment. Digital fundus images were obtained in 1013 eyes. However, in 22 (2.2%), significant lenticular opacities prevented grading of poor quality images.

All these 22 patients were then examined by the residents using indirect ophthalmoscope, and no diabetic retinopathy was observed among them.

The remaining 991 eyes (991 images) were graded by the retinal specialist at the base hospital. No diabetic retinopathy was found in 802 eyes (90.9%) and diabetic retinopathy in 189 eyes (19.1%). Of the 189 eyes with diabetic retinopathy, mild non-proliferative diabetic retinopathy was observed in 103 eyes (54.4%), moderated non-proliferative diabetic retinopathy in 45 eyes (23.8%), severe non-proliferative diabetic retinopathy in 11 eyes (5.8%), and proliferative diabetic retinopathy in 30 eyes (15.8%). Diabetic macular edema was noted in 52 eyes (27.5%): 17 eyes (8.9%) had mid macular edema; 10 eyes (5.2%), moderate; and 25 eyes (13.2%), severe. Besides DR, other retinal findings included retinitis pigmentosa (1 patient), retinal hole (posterior to equator) without retinal detachment (1 eye), and dry age-related macular degeneration (3 eyes).

Since sight-threatening DR was recognized by screening in 28 patients, they were recommended to visit the base hospital for further evaluation and treatment. Of these, 19 (68%) reported for comprehensive eye evaluation including fundus evaluation with binocular indirect ophthalmoscope and slit-lamp biomicroscope. At the base hospital, sight-threatening DR was identified in 32 eyes: PDR in 10 eyes, severe DME with NPDR in 22 eyes. Non-sight threatening DR was identified in 2 eyes and no DR in 3 eyes; one patient was one-eyed.

Both unweighted K value and single measure interclass correlation (ICC) were calculated for estimating grading-agreement between telehealth programme and indirect ophthalmoscopy (**Table 1**). The level of agreement was good across the compared categories: any DR present versus absent (K= 0.79, 95% CI 0.68-0.88), PDR versus NPDR (ICC=0.73, 95% CI 0.53-0.86), sight-threatening DR present versus absent (ICC=0.76, 95% CI 0.63-0.85).

Discussion

As the prevalence of diabetes increases in the next 2-3 decades, so will diabetic retinopathy. The only way to prevent diabetic retinopathy related visual loss is to develop diabetic retinopathy screening models, especially for those who do not have access to health care delivery or who live in remote areas. A developing country like India must organize telehealth programs in rural areas to render these models popular, cost effective, and useful to society. This study investigated the effectiveness of telehealth program for diabetic retinopathy in rural India.

The use of digital images for screening of Diabetic Retinopathy is well-proven.[9-11] While most telemedicine models reported earlier used Internet to transmit images[9-11], we preferred to use the satellite mode because the lack of necessary Internet infrastructure in the villages and known technical feasibility of transmitting images by a mobile van. The Technical Working Group (TWG) for standardization on Telemedicine in India recommends that satellite link is the best option to connect a remote site with high bandwidth pipe in the shortest possible time.[12] Satellite mode offers several advantages: using the wireless telemedicine system makes medical personnel and other subjects relatively free and not bound by any fixed location; transmission of high resolution images almost instantaneously (real time) ensures excellent quality images; interaction is possible between the retinal specialist and the photographer if a repeat image is needed or the image of a different field is needed; and finally, interaction between the ophthalmologist and a patient fosters a positive relationship between a care-provider and a care-receiver. In Canada, the satellite mode was used to transmit digital images from a northern Alberta community to a tertiary care center at Edmonton.[13] Telehealth program for diabetic retinopathy as adopted in this study was cost-effective as the satellite connectivity was provided free by the Government of India.

The American Academy of Ophthalmology had recommended that single-field fundus photography was not an adequate substitute for a comprehensive ophthalmic examination. However, level I evidence suggested that single field image could serve as a screening tool for diabetic retinopathy to identify those patients who needed referral for further ophthalmic evaluation and treatment .[14] In the present screening protocol, we used single-field fundus photography centered midway between the centre of the macula and the disc. A non-mydriatic fundus camera was used in this pilot study because of its portability.

Table 1: Agreement between Telediagnosis and Indirect ophthalmoscopy observations

	Telediagnosis	Indirect Ophthalmoscopy	κ/ICC
DR Vs NDR			
N = 37 (Eyes)			
DR	35	34	
NDR	2	3	κ = 0.79 (95% CI 0.68-0.88)
One eye with NDR was classified as DR by telediagnosis			
PDR Vs NPDR			
N = 34 (Eyes)			ICC = 0.73
PDR	12	10	(95 % CI 0.53-0.86)
NPDR	22	24	
Two eyes with NPDR were classified as PDR by telediagnosis.			
ST Vs NST			
N = 59 (Observations)*			ICC = 0.76
ST	37	32	(95 % CI 0.63-0.85)
NST	22	27	
Five eyes with NST were classified as ST by telediagnosis.			

DR: Diabetic Retinopathy, NDR: No Diabetic Retinopathy, PDR: Proliferative Diabetic Retinopathy, NPDR: Non-Proliferative Diabetic Retinopathy, ST: Sight-threatening, NST: Non Sight-threatening, κ: Kappa coefficient, ICC: Interclass Coefficient Correlation.
*Observations mean PDR or PDR & severe diabetic macular edema or severe diabetic macular edema & NPDR.

Intraocular pressure (IOP) was measured with Schiotz tonometer before the digital images. It is not clear whether or not this step could have influenced the corneal clarity and subsequent quality of digital images. The approximate time interval between the measurement of IOP and digital photograph was 30-40 minutes (time for pupillary dilatation). Therefore, it is very unlikely that the indentation effect of tonometer plate would last long enough to compromise on the quality of the digital photograph. Our rate of ungradable photograph of 2.2% (essentially due to lenticular opacity) appeared to be less than that reported by others (5%). [15] This was in accordance with the British Diabetic Association (BDA) guidelines for screening for diabetic retinopathy.[15] In addition, digital images were obtained after the pupillary dilatation; pupillary dilatation significantly reduced the proportion of un-gradable photographs: from 26% to 5%.[15]

One of the major limitations of this pilot study was the lack of the validation to assess the ability of telescreening (online satellite transmission) to detect the described levels of diabetic retinopathy. Future studies should focus on comparing the results with the gold standard, namely ETDRS stereo, seven-field, film photography for each patient. This would help in assessing whether or not interpretation of digital imaging was correct, as well as the proportion of over or under-diagnosing (false positive or false negative) diabetic retinopathy.

Another limitation of this pilot study was the drop out rate of 32%, i.e, those not reporting to the base hospital for further evaluation despite being told as having sight-threatening diabetic retinopathy on telediagnosis. To minimize this drop out, we need to counsel and educate patients stressing repeatedly the need for such examinations in preventing severe visual loss due to diabetic retinopathy.

In this study, diabetic macular edema was classified according to the proposed classification of American Academy of Ophthalmology.[7] This obviates the need for stereoscopic photographs that require more technical skill and more time. Those who were suspected to have macular edema, however, had their fundus evaluation done on slit-lamp biomicroscopy besides indirect ophthalmoscopy.

Agreement between the presence and absence of diabetic retinopathy was good (K = 79%). However, the agreement for sight threatening diabetic retinopathy as determined by ICC was 0.76 (95% CI 0.63-0.85). This is because of a discrepancy in the level of severity of diabetic retinopathy as judged by telehealth program versus indirect ophthalmoscopy. Three cases were classified as moderate DME (on screening) but they had severe DME when they were diagnosed later at the base hospital. One case was graded as severe NPDR instead of PDR; 2 cases, as severe NPDR, instead of mild or moderate NPDR; and one eye of hypertensive retinopathy was misdiagnosed as moderate NPDR.

Diabetic retinopathy was evident in 19% of rural diabetics. This correlated well with previous studies that found the prevalence of retinopathy to be 10.5% - 20.4%. [2,16] We also observed that 73.6% (95%CI 0.70-0.77) of the rural diabetics had never undergone eye examination. Therefore, it seems prudent to take a screening program at their doorsteps to prevent diabetes-related blindness.

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