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Original Article

Diagnostic accuracy of direct ophthalmoscopy for detection of diabetic retinopathy using fundus photographs as a reference standard

Shahid Ahsan [a], Abdul Basit [b,*], Kazi Rumana Ahmed [c], Liaquat Ali [d], Fariha Shaheen [e], Muhammad Saif Ulhaque [f], Asher Fawwad [g]

[a] Department of Biochemistry, Hamdard College of Medicine and Dentistry, Hamdard University, Karachi 74600 Pakistan
[b] Department of Medicine, Baqai Institute of Diabetology and Endocrinology, Baqai Medical University, Plot No. 1-2, II-B, Block 2, Nazimabad, Karachi 74600, Pakistan
[c] Department of Health Education and Health Promotion, Bangladesh Institute of Health Sciences, Dhaka, Bangladesh
[d] Bangladesh Institute of Health Sciences, Dhaka, Bangladesh
[e] Research Department, Baqai Institute of Diabetology and Endocrinology, Baqai Medical University, Plot No. 1-2, II-B, Block 2, Nazimabad, Karachi 74600, Pakistan
[f] Department of Medicine, Baqai Institute of Diabetology and Endocrinology, Baqai Medical University, Plot No. 1-2, II-B, Nazimabad No. 2, Karachi 74600, Pakistan
[g] Baqai Medical University, Research Department, Baqai Institute of Diabetology and Endocrinology, Plot No. 1-2, II-B, Nazimabad No. 2, Karachi 74600, Pakistan

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ABSTRACT

Aims: To determine the diagnostic accuracy of direct ophthalmoscopy for the presence and severity of diabetic retinopathy (DR) using fundus photographs as a reference standard.
Methods: Patients with type 2 diabetes attending the outpatient department (OPD) of a tertiary care diabetes center, from October 2009 to March 2010 were recruited in the study after obtaining signed informed consent. Patients with type 1 diabetes and gestational diabetes or having eye problems were excluded. After checking visual acuity, direct ophthalmoscopy of each eye was done by diabetologist, followed by photography of two fields of retina by fundus camera. DR was graded by a retinal specialist, according to International Diabetic Retinopathy Disease Severity Scale. According to severity, patients with DR were grouped into non-sight threatening diabetic retinopathy (NSTDR) and sight threatening diabetic retinopathy (STDR). Sensitivity and specificity of direct ophthalmoscopy for detection of any retinopathy, NSTDR and STDR was calculated.
Results: A total of 728 eyes were examined by direct ophthalmoscopy as well as fundus photography. Sensitivity (95% CI) of direct ophthalmoscopy for any retinopathy, NSTDR and STDR was found to be 55.67% (50.58–60.78), 37.63% (32.67–42.59) and 68.25% (63.48–73.02) respectively. Whereas, specificity of direct ophthalmoscopy was found to be 76.78% (72.45–81.11), 71.27% (CI: 66.63–75.91) and 90.0% (86.93–93.07) for any retinopathy, NSTDR and STDR respectively.
Conclusion: The sensitivity and specificity of direct ophthalmoscopy performed by the diabetologist for the presence and severity of DR was lower compared to the recommended level of sensitivity and specificity of a screening test of DR.

1. Introduction

Pakistan is encountering a rapidly growing epidemic of diabetes. With a population of 180 million, currently nearly 7 million people in the country have diabetes. The number is expected to increase nearly to 13.8 million people with diabetes by the year 2030 [1,2]. The escalating prevalence of diabetes increases the risk of diabetic complications [3]. These complications have a devastating impact on the quality of life of a person and also place a significant burden on the health care cost [4].

Diabetic retinopathy (DR) is one of the most important diabetes induced microvascular complications and a leading cause of visual disability and acquired blindness [5]. It is responsible for 4% of blindness in type 1 and 1.6% blindness in patients with type 2 diabetes [6,7]. Global data supports the assumption that DR will

* Corresponding author. Tel.: +92 21 36688897/36608565/36707179; fax: +92 21 36608568.
E-mail address: research@bideonline.com (A. Basit).

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become one of the most important causes of blindness in the future [8–12]. This postulation was also supported by the observation from India. Diabetic retinopathy was the 17th commonest cause of blindness twenty years ago in India that ascended to the 6th position in the year 2005 [13]. Increasing prevalence of retinopathy among patients with diabetes makes it a public health problem and a condition amicable for screening [14]. Screening for DR is done by various techniques [15]. There are two important factors in the screening of diabetic retinopathy, the method by which screening was performed and the skill of the health professionals by whom procedure was carried out.

Due to limited resources, spending on the treatment of patients with diabetes in Pakistan is inadequate [16]. Screening for retinopathy is carried out using direct ophthalmoscopy by the diabetologist or the ophthalmologist even in the tertiary care diabetes centers [17–21]. Hence, this study was conducted to estimate the diagnostic accuracy of direct ophthalmoscopy for the detection of diabetic retinopathy using fundus photographs as a reference standard.

2. Methodology

This cross-sectional study was conducted at Baqai Institute of Diabetology and Endocrinology (BIDE), a tertiary care diabetes center, from October 2009 to March 2010. Patients were recruited from the Out-patient department of BIDE after taking signed informed consent. Ethical approval for the study was taken from the institutional review board of BIDE.

2.1. Patients

All diagnosed patients with type 2 diabetes of either sex, ≥30 years of age were invited to participate. Patients with type 1 and gestational diabetes or having eye problems such as cataract, glaucoma and corneal opacities were excluded from the study. The algorithm for selection of study sample is given in Fig. 1. Data on demographic, anthropometric, clinical and biochemical parameters were collected form each recruited patient (Table 1).

2.2. Reference standard

Screening of retinopathy is done by a variety of modalities. Among all fluorescein angiography (FA) and seven field stereoscopic 30° fundus photographs are considered the modalities of choice for detecting the earliest signs of diabetic retinopathy [22].

Table 1
Demographic, anthropometric, clinical and biochemical characteristics of study participants n = 366.

Variables	*n* = 366 Mean ± SD
Age (years)	48.8 ± 8.0
Male/female *n* (%)	137/229 (37.4/62.6)
Duration of diabetes (years)	9.17 ± 6.51
Body mass index (kg/m^2)	28.64 ± 5.16
Diastolic blood pressure (mmHg)	81.26 ± 11.21
Systolic blood pressure (mmHg)	128.85 ± 20.89
Fasting blood sugar (mg/dl)	164.85 ± 58.87
Random blood sugar (mg/dl)	198.43 ± 70.03
HbA1c (%)	9.73 ± 3.28
Total cholesterol (mg/dl)	181.51 ± 41.75
Triglyceride (mg/dl)	177.25 ± 63.57
HDL (mg/dl)	41.8 ±8.07
LDL (mg/dl)	108.23 ± 28.193
Serum creatinine (mg/dl)	1.07 ± 0.42

Data presented in *n* (%) or mean ± SD.
HDL = high density lipoproteins.
LDL = low density lipoproteins.

FA is an invasive procedure. It carries the risk of serious complications thus not a preferred screening modality in usual clinical practice [23]. Similarly, stereoscopic 30° fundus photographs of seven fields of retina evaluated primarily in ETDRS, is time consuming and expensive. It is therefore not considered an appropriate technique for routine screening uses [24]. Despite these limitations, retinal photographs were widely used as screening tool in both randomized control trials (RCT) as well as in epidemiological studies with modifications. In the landmark United Kingdom Prospective Diabetes Study (UKPDS) screening for retinopathy was done by fundus photography. However the number of retinal fields evaluated for the presence of retinopathy in this study was reduced from seven to four ETDRS fields. In order to secure time and to make photography technique further cost effective, in the multicentre EURODIAB study two fields of retina were validated against stereoscopic 30° fundus photographs. In 30° stereo-photographs seven pairs of photographs were obtained and graded for each eye of each patient. In contrast in the EURODIAB scheme four images per patient were graded. Although both techniques have 100% agreement for detection of retinopathy, screening by two fields is preferred over 28 photographs of the modified Airlie House system due to restricted utilization of resources [25,26]. Several methodological studies documented that the area covered by two field of retinal photograph (macula center and optic nerve center field) has sensitivity and specificity comparable to that of the gold standard, seven field 30° photographs. This is because the macula centered photograph not only covers the macula but also extends from the optic disc to the temporal retina and the second, the optic disc field, covers the region from the disc to the nasal retina. These fields surround most of the other standard retinal fields which are important for looking the early sign of retinopathy and neo-vascularization [27–29]. Screening of retinopathy by fundus photography is the modality of choice in countries like England and Wales where screening was done by single 45-degree macula-center digital retinal photography, supplemented with a disc-center field. With this approach, the sensitivity for referable diabetic retinopathy has been demonstrated to lie within the range of 78–100% with specificity of 86–100%, respectively [30]. Thus in the present study two fields of retinal photographs, one center to macula and other center to optic disc of each eye was taken as a reference standard (Fig. 2).

2.3. Grading of diabetic retinopathy

Grading of Retinopathy was done according to International Diabetic Retinopathy Disease Severity Scale [31]. This classification was based on the modified Airlie House classification scheme used in the Early Treatment Diabetic Retinopathy Study (ETDRS).

2.4. Ophthalmic examination

2.4.1. Ophthalmoscopy

Screening for retinopathy is a routine procedure in BIDE. All the patients attending the out patient department of BIDE were screened for retinopathy by their respective physicians. Best corrected visual acuity was recorded with an internally illuminated Snellen's chart. One drop of 1% phenylephrine was administered in both eyes of the patients. After 30 min pupils were checked for dilatation. When pupil dilated completely fundoscopy of each eye was done in a dark room with Keeler's ophthalmoscope. Presence of signs of retinopathy according to International Diabetic Retinopathy Disease Severity Scale criteria in each eye (right or left) was recorded. After ophthalmic examination by ophthalmoscope, drops for reversal of mydriasis were instilled in each eye. Both the patient and the investigator were blind to the result of index test (direct ophthalmoscopy).