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A Community-Based Telescreening Program to Evaluate Prevalence of Diabetic Retinopathy in Self Reported Diabetic Patients Attending Primary Health Care Hospital in Rural Population in Central India

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Abstract: ***Objective: The aim of the study was to estimate the prevalence of diabetic retinopathy in a rural population at a PHC using fundus on phone. Design: A community-based cross-sectional study. Participants: 1133 patients were enrolled in a district of Nagpur in Central India. Methods: All patients attending the OPD of PHC with self-reported diabetes underwent examination at the base hospital. The fundus of all patients were photographed using fundus on phone and images were uploaded to cloud via smartphone application. The diagnosis of diabetic retinopathy was based on Early Treatment Diabetic Retinopathy Study. Main Outcome Measures: This included age, gender prevalence of diabetic retinopathy, and correlation of prevalence with duration of disease and history-based risk factors. Results: The prevalence of DR in the population with diabetes mellitus was 10.76% (95% CI) and on the basis of age was maximum in 61-70 years followed by 51-60 years. History-based variables that were not associated with increased risk of DR included gender (men and women are at equal risk); history of IHD, Stroke and smoking status; history of HTN is a risk factor; longer duration of diabetes had higher chance of developing retinopathy. Differences in the socioeconomic status greatly influenced the occurrence of DR. Conclusions: The prevalence of DR was 10.76% in rural population in self-reported diabetics. The combination of affordability, portability easy transmission of images using fundus on phone provides a platform not only for in clinic use but also for mass screening programme in India.***

Keywords: Diabetic Retinopathy, Hypertension, Ischemic heart disease, Fundus on phone

1. Introduction

Diabetes is a major public health problem in India. Diabetic retinopathy (DR) is an important cause of preventable blindness. We need to understand that DR has a chronic course with a long latent phase. Up to 98% of DR-related visual loss can be avoided by early screening and prompt management. The prevalence of DR is rising at a terrifying rate in India. The epidemiology of DR remains underreported due to the paucity of dilated fundus examinations in routine examinations. Recently, R.P. Center for Ophthalmic Sciences conducted the National Diabetic Retinopathy Rapid Assessment of Avoidable Blindness (RAAB) Survey 2015–2019, under the aegis of the Ministry of Health and Family Welfare, Government of India. The prevalence of DR in patients with diabetics came out to be 16.9% in that survey [1] This calls for the development of a consolidated DR screening and management program within the ongoing healthcare system in India.[2] National Program for Control of Blindness (NPCB) currently depends on screening of DR in a high risk population in India, which focuses on early diagnosis, referral, and management at every possible point of contact of the patient. Most effective strategy for DR screening is combination of mydriaticretinal photography with indirect ophthalmoscopy. [3] Lack of DR screening equipment at the primary and secondary level of healthcare system and absence of prompt referral mechanisms often leads to overcrowding of patients at the tertiary healthcare institute. These can be managed by the implementation of non-mydriatic fundus cameras, smartphone technology, and teleophthalmology solutions which can be performed by trained healthcare providers. A similar strategy has shown success in various screening programs for retinopathy of prematurity[4]Telemedicine aligns well with the 'Triple Aim' objectives to improve the health of population, improve the patient experience of their care, and reduce per capita cost of healthcare. At the primary level facility, early recognition of diabetic patients from the community should always be emphasized and a prompt referral system should be ensured to refer all diagnosed cases of diabetes to secondary or tertiary level for further diagnoses and treatment of DR.[3] Amongst non-communicable diseases, diabetes is the most prevalent disease which imposes a major burden on health systems. In the year 2017, 425 million people were reported with diabetes and will increase to 629 million by 2045, according to International Diabetes Federation (IDF).[5] Globally, India is set to develop as the capital of diabetes mellitus. In India, 31.7 million people have been affected by diabetes mellitus as reported by WHO. By 2030, this figure will account to 79.4 million, the largest number in any nation in the world. Over a period of time, nearly two-third of all long standing

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Type 2 and Type 1 diabetics are predicted to develop diabetic retinopathy (DR).[6-8] In India prevalence of diabetic retinopathy reported by recent studies were 18.1%, 17.6%, 10.6%, 26.2% and 22.58% respectively. [9-13] Most of these studies were conducted in southern states of India. A nationwide cross-sectional study reported prevalence of Diabetic retinopathy as 21.7% and the risk factors with increased prevalence were male gender, age > 40 years, insulin user and history of nephropathy[14] Diabetic Retinopathy is featured as signs of retinal ischemia or of increased retinal vascular permeability. Loss of vision result from several mechanisms, including neovascularization leading to vitreous haemorrhage and retinal detachment, macular oedema and retinal capillary non-perfusion[15]Our study utilizes a novel, indigenous, sleek smart phone based device for retinal colour photography which can be used for screening of DR both in the clinic and well as in PHCs. As per our knowledge there is no study conducted to determine the prevalence and to generate awareness about the Diabetic retinopathy in central India particularly in Nagpur district. Our study aims to detect the prevalence of DR among self reported diabetes in PHC's across the bhandara district of Nagpur.

2. Material and Methods

A community -based cross sectional study of diabetic patients was conducted for duration of 3 Months (Oct 2020 to Dec 2020) and all diabetic patients attending the PHCs of bhandara district of Nagpur, Maharashtra were enrolled. A structured protocol was followed for screening of patients. All patients with known diabetes mellitus were included and all non-diabetic patients, Narrow angle suspect and patients with media opacity were excluded from the study. An informed consent was taken and findings were recorded in given proforma. All the questions for eliciting history were administered to the patient in his/her own language. Random blood sugar was noted. Blood pressure was measured by sphygmomanometer, with the patient in the sitting position. Snellens charts were used to assess visual acuity. All the instruments were calibrated before the start of the study. Data was collected by one ophthalmologists and two optometrists who had received special training in the procedures of this study. It included uncorrected visual acuity and best corrected visual acuity, complete anterior segment examination and dilatation of pupil unless contraindicated because of risk of angle closure. After dilatation, stereoscopic fundus examination was done by fundus on phone and images were uploaded to cloud via smartphone application and grading of retinopathy was done according to ETDRS classification[18] Visual Impairment and blindness were defined as per WHO criteria as good (visual acuity ≥ 6/12), mild visual loss (<6/12), moderate visual loss (<6/18), severe visual loss (<6/60).[19]

Statistical Analysis

All statistical analysis was performed by using SPSS 25th version and MICROSOFT EXCEL 2013. Mean & Standard deviation was analysed for descriptive statistics. Tests for significance such as x2 tests, t tests, and z tests were applied appropriately. The prevalence of DR in the study population was estimated with 95% confidence interval, fisher exact test and the Chi-square test was used to explore associations with gender, age duration of diabetes, insulin use, and other end-organ disease.

3. Results

Out of 1211 subjects, 1133 patients enrolled for the screening programme using fundus on phone and 78 patients were excluded due to poor quality of images. 51.72% (n=586) were male and 48.27% (n= 547) were females and prevalence of DR was 10.75% and 10.78% respectively. The overall prevalence of DR in subjects with diabetes mellitus was 10.76%. The mean age was 58.66+\- 10.634 years. Mean RBS was 161.17+\- 65.436 mg/dl. Prevalence of DR among subjects with diabetes between 10 to 20 and 21 to 30 years was zero ; for those between 31 to 40 years was 9.52%; 41 to 50 years of age was 9.50%; for those between 51 to 60 years of age, the prevalence was 10.91%; for those between 61 to 70 years of age, the prevalence was 12.95%; and for those older than 71 years, the prevalence was 6.73% (p-value 0.6).The prevalence of DR on the basis of duration of dm was 9.75% in first 5 years; 14.45% in 6 to 15 years; 13.98% in 16 to 25 years; 14.28% more than 25 years of Diabetes mellitus. The prevalence of DR in patients on insulin were 0.0% (n= 0) compared with 11.09% (n=119) among those who were taking OHA and 5.66% (n=03) in patient noncompliance patients (p-value 0.66). Out of 1133 subjects 90.29% (n= 1023) were hypertensive and 9.70% (n=110) didn't had HTN as a risk factor out of which prevalence of DR was 11.04% and 08.18% respectively. 7.23% (n=82) were associated with IHD and 92.76% (n=1051) were not associated with IHD as a risk factor out of which prevalence of DR was 7.31%% and 11.03% respectively. 2.47 %(n=28) had history of stroke episode in the past and 97.52% did not had any history of previous episode of stroke out of which prevalence of DR was 10.71% and 10.76% respectively. 8.12% (n=92) had positive history of smoking while 91.87% (n=1041) had no history of smoking out of which prevalence of DR was 11.04% and 7.60% respectively. Only 4.58% (n=52) had prior history of admission to the hospital and 95.41% had no history of prior admission to hospital. 8.29 % (n= 94) subjects belong to lower class; 37.68% (n= 427) subjects belong to lower middle class; 49.42% (n=560) subjects belong to upper lower class; 4.50 % (n=51) subjects belong to upper middle class; 0.08% (n=1) subjects belong to upper class. Out of which prevalence of DR was 12.76%; 11.24%; 9.82%; 13.72% and 0% respectively. Out of 1133 subjects 10.76% (n=122) had DR according to ETDRS Classification out of which 31.96% (n=39) had Mild Non- Proliferative Diabetic Retinopathy, 42.62% (n=53) had Moderate Non-Proliferative Diabetic Retinopathy, 4.09% (n=5) had Severe Non- Proliferative Diabetic Retinopathy, 5.73% (n=8) had Proliferative Diabetic Retinopathy, 18.03% (n= 22) had Clinically Significant Macular Edema.

4. Discussion

Over the past decades, many cross-sectional studies have been conducted to ascertain the prevalence of DR in the diabetic population in various regions of the country and world. Prevalence provides a cross-sectional snapshot of morbidity at that point or period. The high prevalence of DR in type 2 diabetic patients imposes a large economic burden.

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Severity of hyperglycemia, duration of diabetes and presence of hypertension are widely recognized as major risk factors for the development of DR. Studies have shown that as the duration of diabetes increases so does the chance of developing DR. In our study the prevalence of DR came out to be 10.76% which is similar to the AIOS study which was 21.27% with a range of 12.27% in the central zone and 34.06% in the north zone. In south India, the previous studies to calculate prevalence were done by Raman et al. (18.1%)[09], Rema et . (17.6%)[10] , Namperumalsamy et al. (10.6%)[11], Narendran et al. (26.2%)[12] and Dandona et al. (22.58%)[13] ,Gadkari SS et al (21%)[14],Balasubramanian Nadarajanmean et al (32.53%)[16] , Padmaja Kumari Rani et al 18% in rural and 17% in urban population[17] The National Urban Diabetes Study (2000) showed the prevalence of diabetes in a population older than 40 years to be 23.8% in 6 cities in India including Chennai, and more recently, the Chennai Urban Rural Epidemiology Study (2003–2004) estimated the prevalence in those older than 40 years to be 30.1%. [27-28] Studies performed across the globe reported varying rates of prevalence such as Lian et al. (39%) in Hong Kong, Rodriguez-Poncelas et al. (12.3%) in Spain, Dawkins et al. (18.6%) in Timor-Leste, Huang et al. (33.9%) in Singapore, Giloyan et al. (36.2%) in Armenia, Hajar et al. (27.8%) in Saudi Arabia, and Dutra Medeiros et al. (16.3%) in Portugal.[20-26]

Uniqueness of our study was that screening programme was conducted on fundus of phone and patients in this study underwent retinal examinations over teleophthalmology; photographic documentation was done in 100% of subjects which is considered as the standard practice in the National Diabetic Retinopathy Screening Service, UK, and the Joslin retina network, USA. Reported benefits of retinal fundus imaging are that they allow better standardization, permanent documentation, and accurate reporting by a reading center; and drawbacks are costs of image acquisition and transmission technologies. Fundus on phone resolves the issues around image capture and transmission and other issues of reading, grading, reporting, and providing advice to patients, and crucially the uptake and utilization of available care in a timely manner. Good image acquisition and efficient image transfer are an integral part of the process of screening. The use of a portable device, fundus on phone, with its own power supply and affordability truly makes it a tool for screening. The unique coupling with a smart phone give access to auto focus, high resolution photography, and a wide range of apps for data storage and transmission at a fraction of the cost of dedicated systems.[14] In our study male and females were equally affected, In contrast other studies male preponderance has been reported by the UKPDS study,[29] the Hyderabad study,[30] and a study of Pima Indians.[31] On categorisation on the basis of age group subjects between 61-70 were majorly affected followed by 51-60 age group followed by 31-40 and 41- 50 followed by > 71 age group and was zero in less than 30 years of age. In our study factors that didn't influence the prevalence of DR significantly were smoking status, history of Hypertension Stroke, Ischemic heart disease. On categorization of DR based on its severity, we observed that the maximum number of patients had Moderate NPDR followed by Mild NPDR followed by CSME followed by PDR and then severe NPDR. In our study the prevalence of DR with respect to socioeconomic status, we observed that upper middle class was majorly affected followed by lower class followed by lower middle class followed by upper lower and then upper class. The cost of care for people with DR depends on the stage of the disease. Increased costs were associated with sight-threatening DR, which often resulted from an increase in the number of intravitreal injections, retinal lasers, hospital visits. In our study prevalence of DR based on the duration of disease was maximum in 6 to 15 years of disease followed by more than 25 years of disease followed by 16 - 25 years of diseaseand is least in first 5 years of disease. In our study prevalence of DR was more in oral hypoglycemics than on insulin. Similar results were reported in American Indians in Oklahoma, the prevalence of DR was higher in those on oral hypoglycemic agents rather than on insulin treatment. [32] In contrast some studies have reported prevalence of DR was higher on those on insulin than on OHA in the study of Pima Indians [31] and in the Beaver Dam study.[33,34]

5. Conclusion

A community-based telemedicine screening program for DR was implemented in a District of Nagpur in Central India & current study focuses on the integration of DM and eye care services, promoting the awareness of DM care providers and patients and applying modern technologies to improve DR care service delivery. Our study estimated the prevalence of DR in Nagpur district to be 10.76%. This information has a great impact on the public health awareness programme highlighting the need for regular eye examination in educating masses with DM. The combination of affordability, portability, easy transmission of images and other features of this fundus on phone system provide a platform not only for in-clinic use but also for planning mass DR screening programs in India.

6. Limitations

The study design was cross-sectional, so we could not take into account of the temporal relationship between potential risk factors and outcomes. Another limitation is its short duration. Moreover, random blood sugar was used instead of HBa1C to assess glycemic control, due to the lack of facilities in the study area.

7. Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient has given his consent for his their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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Table 1: Prevalence of Diabetic Retinopathy in Study Population

Variables	Total Population (N= 1133)	Prevalence of Diabetic Retinopathy (%) (N=122)	P-Value
Age (YRS)			
Oct-20	04 (0.35%)	0	
21-30	07 (0.617%)	0	
31-40	63 (5.56%)	6 (9.52%)	
41-50	221 (19.50%)	21 (9.50%)	0.6**
51-60	348 (30.71%)	38 (10.91%)	
61-70	386 (34.06%)	50 (12.95%)	
>71	104 (9.17%)	7 (6.73%)	
Mean Age +/- SD	57.97±10.67	58.66±10.634	
Mean RBS (mg/dl)	145.23±65.436	161.17±65.436	
Gender			
Male	586 (51.72%)	63 (10.75%)	0.9*
Female	547 (48.27%)	59 (10.78%)	
Treatment Methods			
OHA	1073 (94.70%)	119 (11.09%)	
Insulin	07 (0.61%)	0	0.66*
Non Compliance	53 (4.67%)	03 (5.66%)	
Smoking Status			
NON-SMOKER	1041 (91.87%)	115 (11.04%)	0.3*
SMOKER	92 (8.12%)	07 (7.60%)	
History of HTN			
Yes	1023 (90.29%)	113 (11.04%)	0.3*
No	110 (9.70%)	09 (8.18%)	
History of IHD			
Yes	82 (7.23%)	06 (7.31%)	0.2*
No	1051 (92.76)	116 (11.03%)	
History of Stroke			
Yes	28 (2.47%)	03 (10.71%)	1.0**
No	1105 (97.52)	119 (10.76%)	
Socioeconomic Status [Kuppuswamy Scale]			
UPPER(I)	01 (0.08%)	00	0.65**
UPPER MIDDLE(II)	51 (4.50%)	07 (13.72%)	
UPPER LOWER(III)	560 (49.42%)	55 (9.82%)	
LOWER MIDDLE(IV)	427 (37.68%)	48 (11.24%)	
LOWER(V)	94 (8.29%)	12 (12.76%)	
Duration of Diabetes (Years)			
0-5	882 (77.84%)	86 (9.75%)	0.23*
6-15	173 (15.26%)	25 (14.45%)	
16-25	43 (3.79%)	06 (13.98%)	
> 25	35 (3.08%)	05 (14.28%)	
ETDRS Classification			
MILD NPDR	39 (3.4%)	39 (31.96%)	
MODERATE NPDR	52 (4.6%)	52 (42.62%)	_
SEVERE NPDR	05 (0.4%)	05 (04.09%)	
PDR	07 (0.6%)	07 (05.73%)	
CSME	22 (1.9%)	22 (18.03%)	

*Chi-square test, **Fisher exact test.

Table 2: Prevalence of diabetic retinopathy relative to duration of diabetes

	Duration of diabetes (years)				
	0-5	06-15	16-25	> 25	p- value
Mild NPDR	31	4	2	2	0.5**
Moderate NPDR	36	11	2	3	0.2**
Severe NPDR	4	1	0	0	0.7**
PDR	5	2	0	0	0.5**
CSME	12	10	0	0	0.007**

**Fisher exact test

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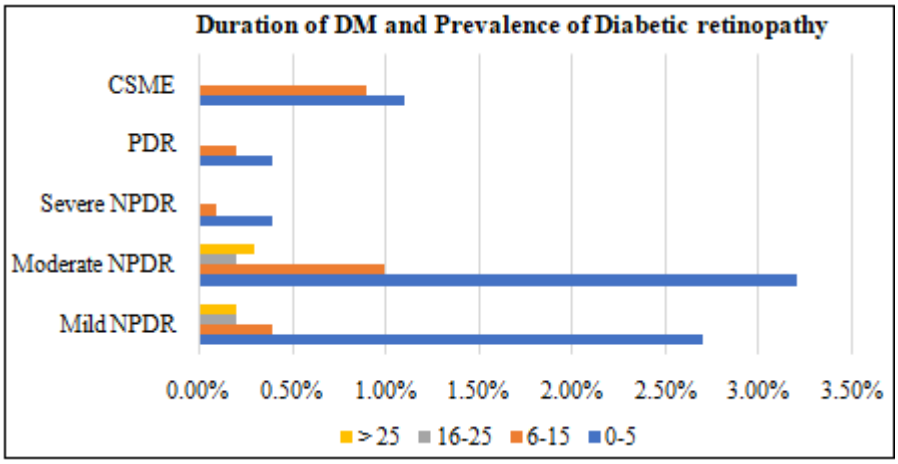
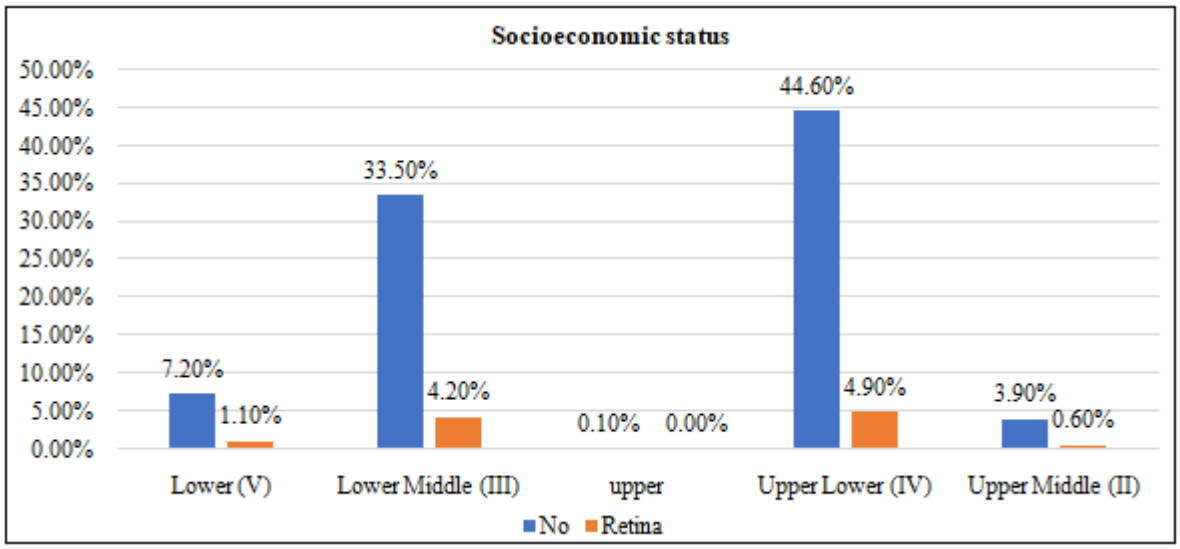
Table 2: Regression Analysis to Study the Effect of Various Risk Factors on Diabetic Retinopathy

Risk factors		95% C.I.		
	Odds Ratio	Lower	Upper	P value
GENDER				
Male				
Female	1.004	0.689	1.462	0.985
SMOKING				
YES	0.663	0.3	1.468	0.311
NO				
HTN				
YES	1.352	0.757	2.415	0.309
NO				
IHD				
YES	1.312	0.675	2.551	0.423
NO				
STROKE				
YES	1.394	0.476	4.087	0.545
NO				
TREATMENT				
YES	2.064	0.634	6.72	0.229
NO				





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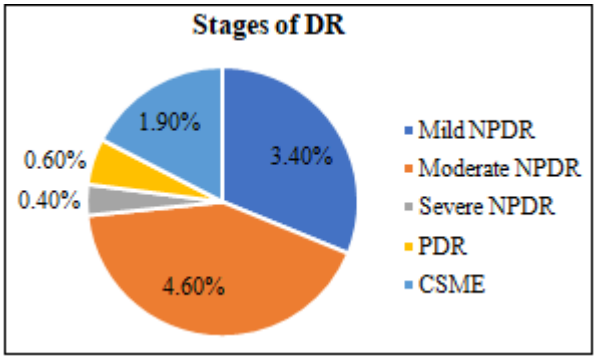

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