

**ORIGINAL RESEARCH ARTICLE****THE PREVALENCE OF DIABETIC RETINOPATHY, RISK FACTORS, VISUAL IMPAIRMENT AND OCULAR STATUS AMONG PATIENTS WITH DIABETES MELLITUS PRESENTING TO BERHAN AINI NATIONAL REFERRAL HOSPITAL, ERITREA: A HOSPITAL BASED STUDY****P Bastola^{1*}, F Kahsay², S Zewengiel³, MM Muguleta⁴**¹ Consultant Ophthalmologist, retina specialist, Berhan Aini National Referral Hospital, Asmara, Eritrea² Medical Director, Consultant Ophthalmologist, Berhan Aini National Referral Hospital, Asmara, Eritrea³ Program Coordinator, National Blindness Prevention Programme (NBPP), Ministry of Health, Asmara, Eritrea⁴ Head, Pharmacovigilance Centre, Ministry of Health, Asmara, Eritrea***Correspondence to:** Dr. Pradeep Bastola, Consultant Ophthalmologist and retina specialist, Berhan Aini National Referral Hospital, Asmara, Eritrea.Email: drbastola15@gmail.com**ABSTRACT**

Diabetic Retinopathy (DR) is the most common ocular complication in the diabetic population and the leading cause of blindness amongst working age group. There is a paucity of data about DR and various factors in Eritrea. The study aimed to find the prevalence of diabetic retinopathy, risk factors, visual impairment and ocular status among patients with diabetes mellitus in Asmara, Eritrea. This was a hospital based, Mixed method, descriptive study, all the consecutive patients attending the retina clinic of the hospital were enrolled in the study from January, 2014 to October, 2016. Early Treatment Diabetic Retinopathy Study (ETDRS) and Modified Airlie House classification were followed to evaluate the various stages of diabetic retinopathy and clinically significant macular edema (CSME). The guidelines developed by International Council of Ophthalmology (ICO) were followed to determine the need for interventions. Of the 506 diabetic subjects attending Berhan Aini National Referral Hospital; 435 (86.0%) subjects had type 2 Diabetes Mellitus (DM). 425 (84.0%) subjects had diabetic retinopathy. Moderate visual impairment, severe visual impairment and blindness due to diabetic retinopathy was observed in 139 (27.1%), 57 (11.1%), 76 (15%) subjects respectively while 234 subjects (46.2%) had normal vision. Hypertension 309 (61%) was the most common risk factor followed by duration of diabetes, occupation and the level of glycosylated Hemoglobin. 481 (95%) of the literate subjects were aware about diabetic retinopathy ($P < 0.01$). 277 (54.7%) subjects needed prompt treatment. There is a high prevalence of DR in patients attending Berhan Aini National Referral Hospital (BANRH). Awareness about diabetic retinopathy was good still the knowledge about primary prevention was not good enough.

Key words: Diabetes mellitus, Diabetic retinopathy, Hypertension, Risk factors, Visual status.**INTRODUCTION**

Diabetic retinopathy (DR) is one of the important causes of visual impairment and blindness in the world and Eritrea is not exception to this global burden¹. The alarming rise in prevalence of diabetes mellitus (DM) is a global public health and economic problem². DR is the most common ocular morbidity in diabetic population and is the leading cause of blindness among working age group². Diabetics are six times more prone to develop cataracts and 1.4 times susceptible to open angle glaucoma when compared with general population³.

DM is one of the priority diseases in "VISION 2020" initiative for the global elimination of avoidable blindness and is also a priority disease in all the developing countries of the world and Africa as well⁴. Early screening of diabetics with potential DR is not top priorities in a country like Eritrea as; preventable causes of blindness still have far more impacts in the general population and general eye health system².

When data is extrapolated from countries with similar socioeconomic status like Eritrea like Nepal, East Timor, Ethiopia, Burundi etc., an estimated national

prevalence of DM in Eritrea is about 4.4%⁵. Lack of awareness about the risk factors and development of DR was found to be coupled with sight threatening visual impairment at first presentation as shown by other studies^{6,7}.

There is a paucity of data regarding DM and DR in general in Eritrea and there is a need of proper data in diabetics to find out the awareness about diabetic eye disease (DED), visual morbidity, associated risk factors and need for interventions amongst the diabetic population to reduce DR related visual problems. This study thus primarily aimed to find out the prevalence of DR, risk factors associated, awareness about development of DR in DM patients and the need for various modalities of interventions in cases with sight threatening DR in urban Eritrea.

METHODS/METHODOLOGY

This was a hospital based mixed method (Quantitative and qualitative) descriptive study done in the retina clinic of Berhan Aini National Referral Hospital (BANRH), Asmara, Eritrea from January, 2014 to October, 2016. All the consecutive patients with diabetes mellitus attending the retina clinic of the hospital were included in the study. Quantitative data for the study was obtained from the patient files, old hospital records of the years 2014, 2015 and 2016, treatment records from the retina clinic and examination reports. All the old files were reviewed from June, 2016 to August, 2016 in the meantime all the consecutive new patients were enrolled in the study. While qualitative data was obtained using a simple questionnaire made for the study.

The assistant in the retina clinic was using the local language to facilitate easy history taking and to further proceed in the study. The study strictly adhered to the tenets of declaration of Helsinki. An informed consent was taken from all the study subjects and an information sheet was given to all the study subjects about the benefits or hazards of the study. Ethical approval for the study was taken from Health Research Proposal, Ethical Review Committee/Board.

A detailed ocular examination starting from the visual acuity and evaluation of fundus after mydriasis was done by two retina specialists. Fundus evaluation was done using direct Ophthalmoscope

and indirect Ophthalmoscopy using +20 Dioptre (D), +78D and +90D lenses. All four quadrants of the retina superior, inferior, nasal and temporal were examined in detail. Macular and foveal region was given a special attention during the fundus evaluation. The significant findings from the fundus were documented and a picture of the fundus was drawn in each case.

Baseline socio demographic characteristics, awareness about DR in DM patients, visual morbidity and visual status of the study subjects, HBA1C values in selected patients, risk factors associated with DM and development of DR, different stages of DR and need for interventions were specifically documented using a well-designed proforma for the study.

World Health Organization (WHO, 1977) classification of visual impairment was followed in the study (Still followed worldwide as a gold standard)

Normal vision: Best corrected visual acuity in the better eye $\leq 6/18$

Moderate visual impairment (VI): Best corrected visual acuity in the better eye $<6/18-6/60$

Severe VI: Best corrected visual acuity in the better eye $<6/60-3/60$

Blindness: Best corrected visual acuity in the better eye $<3/60$ or visual fields less than 10 degrees

Modified Airlie House classification and Early Treatment and Diabetic Retinopathy Study (ETDRS) were used for evaluation of different stages of DR and macular edema in the study subjects⁸⁻¹¹.

Non proliferative DR

Mild non proliferative diabetic retinopathy (NPDR) : Presence of at least one retinal micro aneurysm, but hemorrhages and micro aneurysm less than those in ETDRS standard photograph No. 2A.

Moderate NPDR: Hemorrhages or micro aneurysms or both greater than and equal to those pictured in ETDRS standard photograph No. 2A. Soft exudates, venous beading, intra retinal micro vascular anomaly (IRMA) are definitely present in mild degree.

Severe NPDR (4:2:1 rule): Hemorrhages or micro

aneurysms in all four quadrants of the retina

Venous beading in at least two quadrants

IRMA in at least one quadrant

Very severe NPDR: Any two or more of the findings listed in severe NPDR reflects very severe NPDR

Proliferative diabetic retinopathy (PDR)

Diabetic retinopathy marked by neo vascularization of the optic disc (NVD) or neo vascularization elsewhere (NVE) in the retina or pre retinal or vitreous hemorrhage by fibrous tissue proliferation is designated as PDR. PDR again was classified as following in the study subjects.

Early PDR: NVD <1/3 or NVE <1/2 disc area

High risk PDR: NVD =>1/3 or NVE =>1/2 disc area or NVD greater than ETDRS standard photograph 10A approximately, with pre retinal hemorrhage or vitreous hemorrhage

Advanced PDR (Advanced diabetic eye disease): Fibrous tissue proliferation in the form of tractional retinal detachment, epiretinal membrane, new vessels in the anterior chamber angle or iris, neo vascular glaucoma (NVG), phthisis bulbi and or absolute blind eye¹⁰.

Clinically significant macular edema (CSME) was defined as following in the study⁸⁻¹⁰

1. Thickening of retina at or within 500 microns from the centre of the macula or
2. Hard exudates with thickening of the adjacent retina located at or within 500 microns from the centre of the macula or
3. A zone of retinal thickening, >1 disc area located at or within 1 disc area from the centre of the macula

International Council of Ophthalmology (ICO) guidelines and American Academy of Ophthalmology (AAO) guidelines were followed for need for active interventions in the study subjects^{8,12}

Category of the patients	Interventions
Severe/Very severe NPDR	Early pan retinal photocoagulation (PRP)
High risk PDR/Advanced PDR	Urgent PRP
CSME involving Centre of macula	Anti VEGFs
CSME not involving centre of the macula	Focal/Grid LASER treatment
Dense non clearing vitreous hemorrhage	Pars plana vitrectomy (PPV)
Tractional retinal detachment (TRD) involving or threatening macular involvement	PPV
Combined tractional and rhegmatogenous retinal detachment (RRD)	PPV
Significant recurrent vitreous hemorrhage despite maximal PRP	PPV

However; other factors supporting the need for PRP included likelihood of poor follow up, poor patient compliance, status of the fellow eye, anticipated cataract surgery, pregnancy and other concomitant risk factor like diabetic nephropathy^{8,11}.

Interventions in the study was done in the form of pan retinal photocoagulation (PRP), focal or grid laser, intra vitreal anti vascular endothelial growth factors (VEGFs) like ranibizumab (1.25 mg in 0.05 ml), bevacizumab and intra vitreal corticosteroids in the form of triamcinolone (4mg) were given by the retina specialist in Berhan Aini National Referral Hospital (BANRH). But due to lack of proper vitreo-retina set up in BANRH, subjects needing surgical treatment in the form of pars plana vitrectomy (PPV) or retinal reattachment surgery with or without retinal endo laser therapy were referred abroad.

The collected data was checked and coded manually and then entered in to the Microsoft Excel, Microsoft word 2013, Statistical Package for Social Services (SPSS) 19, Stata 12, 13. Quantitative data was analyzed using SPSS software while to analyze qualitative data Stata 12, 13 was used. When needed qualitative data was converted to quantitative data for easy analysis. Relevant data was analyzed, a probability value (P value) less than or equal to 0.05 was considered significant. A Statician was consulted when and where necessary.

RESULTS

The age of the study subjects ranged from 14-90 years, mean age of the patients was 58.8 (+- 12.9). Gender wise male 338 subjects (66.8%) outnumbered the females. More than three fifth study subjects were from Asmara, Eritrea. 390 subjects (77.9%) were literate, Occupation wise office workers and housewives were more common amongst the study subjects 34.9% and 21.3% respectively. 435 (86%) study subjects had type 2 DM whereas; only 124 subjects (24.5%) had a positive family history. Mean duration of DM in the study subjects was 15.7 (+- 7.9) years; while mean glycated hemoglobin levels in percentage in selected subjects was 7.8 (+- 1.4) (Table 1,2). Only literacy ($P<0.01$) and duration of DM ($P<0.001$) were statistically significant risk factors (Table 3).

481 subjects (95%) were aware about DR (Table 1, 2) and main source of awareness were the health workers in 380 subjects (75.0%). Hypertension was the commonest co-morbid risk factor present in 309 (61%) followed by obesity, diabetic neuropathy and diabetic nephropathy, but hypertension was not statistically significant in developing DR in the subjects ($P=0.29$).

Table 1: Risk factors associated with diabetes and DR in the study subjects

Gender wise distribution of the study subjects (n=506)		
Gender	Numbers	Percentage (%)
Male	338	66.8
Female	168	33.2
Total	506	100
Address of the study subjects		
Address	Numbers	Percentage (%)
Urban Eritrea	316	62.4
Rural Eritrea	190	37.6
Total	506	100
Age in range, mean age and standard deviation (SD)		
Age in range (years)	14-90 years	
Mean age of the study subjects (years)	58.8 (SD 12.57)	
Educational status of the study subjects (n=506)		
Status	Number of study subjects (%), n=506	
Illiterate	112 (22.1)	
Elementary	100 (19.8)	
Junior School	72 (14.2)	
High School and above	222 (43.9)	
Total	506 (100%)	
Occupational status of the study subjects (n=506, %)		
Office workers	176 (34.8%)	
House wives	108 (21.3%)	
Business	106 (20.9%)	
Farmers	38 (7.5%)	
Others	78 (15.4%)	
Total	506 (100%)	
Mean duration of DM (SD) and type of DM in the study subjects (n=506, %)		
Mean duration of DM (in years and SD)	15.7 (SD=+7.9)	
Type 1 DM	71 (14.0%)	
Type 2 DM	435 (86%)	
Total	506 (100%)	
Family history of the study subjects with regard to DM (n=506, %)		
Family history	Number (%)	
Positive family history	124 (24.5)	

Negative family history	382(75.0)
Total	506 (100%)
Systemic risk factors and co-morbidity in the study subjects (n=506, %)	
Risk factors	Number of subjects (%)
Hypertension***	309 (61)
Obesity	48 (9.5)
Diabetic Neuropathy	20 (4)
Diabetic Nephropathy	20 (4)
Cardiac problem	18 (3.6)
Cerebrovascular problem	16 (3.1)
Chronic kidney disease	4 (0.8)
Others	71 (14.0)
Total	506 (100)
Awareness about Diabetic Eye Disease (DED) among the study subjects	
A w a r e n e s s about DED	Number of Subjects (%)
Aware	481 (95)
Not aware	25 (5)
Total	506 (100%)

*** P value=0.29, the table showing high prevalence of hypertension in the study subjects, it was not statistically significant in development of diabetic retinopathy.

Table 2: Various factors associated with awareness about diabetic retinopathy

Variants	Examined/Tested	Multivariate odds ratio (Confidence interval 95%)	Probability value (P value)
Gender	Male versus Female	0.70 (0.21-1.0)	0.2
Education*	Literate versus illiterate	0.36 (0.16-0.83)	0.014
Family history	Yes versus no	1.54 (0.55-4.26)	0.4
Diabetic retinopathy	Present versus no	0.47 (0.19-1.14)	0.09
Hypertension	Yes versus no	0.92 (0.41-2.01)	0.83
Address	Urban versus rural	1.38 (0.441-2.01)	0.43

*The table clearly showing that, the main factor contributing for awareness about diabetic eye disease in the study subjects was the literacy (P=0.01)

Table 3: Prevalence of diabetic retinopathy and its association duration of diabetes mellitus and gender

Variants	Study Subjects	DR	%	P value
Gender				0.7
Male	338	287	85.0	
Female	168	138	82.1	
Total	506	425	84	
Duration of diabetes mellitus in the study subjects				0.001
<5 Years	70	42	60.0	
6-10 Years	96	70	72.9	
11-15 Years#	114	92	80.7	
16-20 Years##	118	110	93.2	
>20 Years**	108	102	94.4	

#, ##, ** Showing high prevalence of diabetic retinopathy in the study subjects, who have had diabetes mellitus for a longer period of time, this finding in the study was statistically significant.

However; there was no difference in the gender for prevalence of diabetic retinopathy.

234 (46.2%) study subjects had normal visual acuity whereas; 272 (53.8%) subjects had visual impairment. 425 (84%) subjects had DR in various stages; whereas 277 subjects (54.7%) of them needed intervention of some kind (Table 4).

Table 4, showing the visual status of the study subjects, various stages of diabetic retinopathy and interventions required.

Visual status of the study subjects (N=506, n=1012 eyes)		
Visual acuity	Right Eye (RE)	Left Eye (LE)
6/6-6/18	238 (47.0%)	230 (45.4%)
<6/18-6/60	135 (26.7%)	143 (28.2%)
<6/60-3/60	57 (11.2%)	57 (11.2%)
<3/60	76 (15.0%)	76 (15.0%)
Total	506 (100%)	506 (100%)
Total eyes	1012 (100%)	
Various stages of diabetic retinopathy, macular edema and severity in the study subjects (N=425)		
Stage of DR	Right Eye (RE)	Left Eye (LE)
Mild NPDR	80 (18.9%)	80 (18.9%)
Moderate NPDR	70 (16.4%)	72 (16.9%)
Severe NPDR	52 (12.2%)	50 (11.8%)
Very severe NPDR	26 (5.1%)	28 (6.6%)
Early PDR	22 (5.2%)	20 (4.7%)
High risk PDR	25 (5.9%)	25 (5.9%)
Advanced PDR	90 (21.2%)	90 (21.2%)
DME	20 (4.7%)	18 (4.2%)
CSME ¥	112 (26.3%)	114 (26.8%)
Various interventions required in the study subjects (N=277, n=554 eyes)		
Interventions	Right Eye (RE)	Left Eye (LE)
Focal or Grid laser treatment	40 (14.4%)	40 (14.4%)

Scatter PRP	42 (15.1%)	42 (15.1%)
Urgent PRP	75 (27.0%)	75 (27.0%)
PRP + Focal or Grid laser	60 (21.7%)	60 (21.7%)
PRP + anti VEGFs	24 (14.4%)	24 (14.4%)
Anti VEGFs only	16 (5.0%)	16 (5.0%)
Pars plana vitrectomy (PPV) and referal	20 (7.2%)	20 (7.2%)

¥ Clinically significant macular edema (CSME) was diagnosed to be overlapping with other stages of DR

Cataract was the most common ocular co-morbid condition followed by pseudophakia without posterior capsular opacification (PCO), refractive error, pseudophakia with PCO and neo vascular glaucoma (NVG).

DISCUSSION

The mean age of study subjects in this study was 58.8 (SD+-12.9), in studies done in Yemen [13] and Nepal⁷, the mean age of diabetic subjects was 54.4 (SD+- 12.6) and 57+- 10.8 respectively, these findings correlated well with the present study. In studies done elsewhere by Mahafouth et al¹³, Rema M et al¹⁴ and Shrestha S et al¹⁵, female predominance was seen in the study subjects; however in the present study gender wise male outnumbered the females. This finding was similar to the findings from studies done by Khandekar R et al¹⁶, Dawit W et al¹⁷ and a study from Nepal⁷. Only reason that could be given to male predominance in the study could be due to more mobility of males and health seeking behavior amongst them (Table 1).

Of all the study subjects approximately 78% were literate, a reason in the study which also made the study subjects aware about diabetic retinopathy. Occupation wise office workers (34.8%), housewives (21.3%) and businessman/woman (20.9%) had higher prevalence of DM, whereas people involved in farming were less affected (7.5%). The tendency to develop DM in subjects involved in office work, house wives and business is mainly due to sedentary lifestyle, less physical activity and early diagnosis. In contrary the lesser prevalence of DM amongst farmers is due to increased physical activity, and poor health seeking behavior amongst them. This finding of the study was comparable to the study done in Nepal¹⁵.

High prevalence of Type 2 DM (86%) in this study is comparable to studies done in other parts of the world with similar socioeconomic status like Eritrea^{7,15,18}. This again signifies the fact that type 2 DM is a growing global public health and economic problem¹ (Table 1).

In the present study; awareness about development of diabetic eye disease in the subjects was very high (95%), this finding was comparable to studies from Kenya¹⁹ and other parts of world^{20,21}. Similar to a study from Nepal⁷, in this study also awareness was even higher amongst literate subjects. An interesting analysis about awareness and DR retinopathy showed literate subjects were aware about developing DR (P=<0.01), whereas gender, hypertension, family history or address did not have any significant role in developing DR (Table 1, 2).

Despite a very high awareness level in the study subjects about development of DED, the study subjects in the present study presented late to the hospital and many subjects needed prompt interventions in various forms. While many subjects from the study population had severe visual impairment or were blind due to DR (Table 4). These findings in the study could conclude that there is inadequate infrastructure or human resources in the community level, district level and zonal level for educating people about DR, screening for DR or treatment and even the literate subjects with DM are not fully aware about the sight threatening complications of DR in urban Eritrea.

The prevalence of DR in the study subjects in the present study was 84% and there was no gender difference in the prevalence rate (Table 3), which is comparable to a study done in Nepal, where the hospital based prevalence of DR in diabetics was 77.6%⁷. However; the prevalence of DR noted in this study was higher than the prevalence noted

in other African countries and nearby Middle East country^{9,22,23}. The high prevalence of DR in the present study probably is due to the late presentation of the diabetic subjects to retina clinic of the study hospital only when the subjects felt visual problems. The other reason contributing for higher prevalence of DR is due to poor referral tendency to the tertiary eye hospital in time by the physicians and ophthalmic technicians as already discussed. Screening diabetic patients for retinopathy poses considerable challenges, particularly in a country like Eritrea, where there is no diabetic retinopathy screening or training programme to the physicians or even to primary eye health workers.

The present study showed that, the longer the duration DM higher the chances of developing DR ($P < 0.001$) (Table 3), this is similar to the existing knowledge about development of DR and other studies also have shown similar findings^{5,7,13,16}. To magnify the existing problem; in the present study, 272 (53.8%) subjects had visual impairment, moderate visual impairment, severe visual impairment and blindness due to diabetic retinopathy was observed in 139 (27.1%), 57 (11.1%), 76 (15%) subjects respectively (Table 4). Whereas 277 (54.7%) subjects needed prompt treatment in the form of pan retinal photocoagulation, focal or grid laser, anti VEGFs, vitreo-retinal surgery or combination of them (Table 4). Blindness from diabetic retinopathy is an emerging factor for the loss of productivity and rising health costs. Visual disabilities among diabetics were considerably higher compared with general population in a study done elsewhere [16]. This presenting visual status in the present study reflects 26.1% study subjects either with severe visual impairment or blind. This information from this study will be very important to achieve the goal of VISION 2020 in Eritrea and about further planning for early detection and treatment of DM patients with DR and will also help to formulate a standard protocol about the management of DR patients.

The main contributing cause for visual impairment in the present study was the stage of DR, almost 82% of the study subjects with DR were already diagnosed to have moderate NPDR, severe NPDR, very severe NPDR, Early PDR, High risk PDR, Advanced PDR, DME and CSME and hence needed prompt treatment. The prevalence of PDR in the current study was

comparable to studies done in Nepal and Yemen^{7,9}. However; in this study the prevalence of CSME was low approximately 26.5% (Table 4); when compared to a study from Nepal, where it was diagnosed in 40% subjects with DR. Low prevalence of CSME could be the reason for subjects presenting to the hospital late in the present study as CSME is one of the most important causes for visual morbidity in diabetic retinopathy⁸.

Severity of DR, macular involvement at the time of diagnosis, status of the fellow eye, likelihood of poor follow up, anticipated cataract surgeries, other concurrent systemic risk factors and advancing age of the study subjects contributed in 277 (54.7%) study subjects needing prompt treatment.

Co-morbid conditions in the study subjects like hypertension, cardiac disease, diabetic neuropathy, obesity, ocular co-morbid conditions like cataract, pseudophakia, glaucoma etc., levels of glycated hemoglobin in the study subjects, age, gender were independent risk factors and did not have any significant association to develop DR.

LIMITATIONS OF THE STUDY

This study was not a population based study and hence suffered from selection bias as the study took place in national referral tertiary eye hospital. Hospital seeking patients were mostly with severe DR hence the sample size of the study was small. Glycated hemoglobin level parameters were not available for all the study subjects.

CONCLUSIONS AND RECOMMENDATIONS

The high prevalence of diabetic retinopathy (84%) in the study could conclude that, these subjects present late to the hospital and is due to diminished vision. Awareness about diabetic retinopathy was good still the knowledge about primary prevention was not good enough. Hypertension was the major modifiable risk factor along with duration of diabetes in these subjects. The duration of diabetes is the only factor contributing significantly in developing DR. Most of the DM patients seeks hospital due to severe visual impairment or after being blind and they require prompt urgent treatment. In the absence of vitreo-retinal set up in the country many subjects require referral to other countries for further management.

RECOMMENDATIONS

- A further study in diabetic clinic at general hospital or community level is recommended to find out the overall prevalence and impact of DR in Eritrea, rural or community set up for study would be ideal.
- A comprehensive training on DR screening should be launched to all the general physicians and eye health workers.
- Awareness programme at community level about DM and DR should be strengthened.
- Basic screening devices like fundus camera, fundus fluorescence angiography, optical coherence tomography and vitrectomy set up is recommended to be in place in the tertiary national eye hospital to avoid dependency and referral to abroad for advanced diabetic eye disease.
- Intra vitreal anti vascular endothelial growth factor (VEGF) should be at least available in the tertiary national eye hospital and all the treating Ophthalmologists should be trained in delivering laser treatment and giving intra vitreal injections in diabetic patients.

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