• Clinical Research •

Frequency of diabetic retinopathy and associated risk factors in Khartoum, Sudan: population based study

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Abstract

• AIM: To assess the frequency and associated risk factors of diabetic retinopathy among Sudanese individuals with diabetes attending Makka Eye complex in Khartoum, Sudan.

• METHODS: The cross sectional hospital based study recruited 316 individuals with diabetes from Makkah Eye Complex Retina Clinic. Standard questionnaire was used to collect demographic data, medical history and life style characteristics. Blood samples were taken to measure HbA1c and lipid profile. Fundus and slit lamp examination were performed for screening of diabetic retinopathy.

• RESULTS: Among 316 participants, 187 (59.2%) were males and 129 (40.8%) were females. The mean age of participants was 58.7±10.5y. The overall frequency of retinopathy was 261 (82.6%). The percentages of the total participants with proliferative diabetic retinopathy (PDR) were 126 (39.9%) and non-proliferative diabetic retinopathy (NPDR) were 135 (42.7%). Importantly, duration of diabetes mellitus (DM) (72.2% of more than 10y), being on oral hypoglycaemic drugs (versus insulin), and hypertension were all significant risk factors for diabetic retinopathy (*P*=0.00, 0.01 and 0.00 respectively). Complications of diabetes like diabetic foot (17.7%), history of amputation (6.7%) and clinically significant macular edema (CSME) (47.4%) of the eyes were all significant risk factors (*P*<0.05). Logistic regression analysis showed that duration of diabetes, hypertension and CSME were found to be absolute risk factors (*P*=0.007, 0.003 and 0.000 respectively). Duration of DM of more than 10y have more than double risk (OR=2.8), while having hypertension triples the risk of retinopathy (OR=3.1).

• CONCLUSION: High rates of diabetic retinopathy are noted among individuals with diabetes attending Makkah Eye hospital in capital Khartoum. Urgent strategies are needed to monitor and treat hypertension and optimize diabetes control in individuals with diabetes. More investment in diabetes services is urgently needed.

• KEYWORDS: diabetes; Sudan; diabetic retinopathy; insulin
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INTRODUCTION

Diabetic retinopathy (DR) is one of the progressive microvascular complications of diabetes, which is characterized by signs of retinal ischemia such as micro aneurysms, haemorrhages, cotton-wool spots (CWS), intraretinal microvascular abnormalities (IRMAs), venous calibre abnormalities, and neovascularization and/or signs of increased retinal vascular permeability[1]. The inevitable consequence of DR is that it does not only lead to visual impairment but can also compromise the ability of individuals to manage successfully their disease[2]. Importantly, diabetes is associated with 25 times increased risk of blindness, especially in those with long duration of diabetes. For instance, in individuals with diabetes for more than 20y, it was estimated that 77% may have degree of retinopathy[3].

Depending on the International Clinical Disease Severity Scale (ICDSS), DR has been classified into proliferative diabetic retinopathy (PDR) which is further classified into mild, moderate, severe, and non-proliferative diabetic retinopathy

(NPDR)[4]. In a systemic review included 62 studies from 21 African countries, showed that the prevalence of retinopathy range from 30.2% to 31.6%; PDR 0.9% to 1.3%, and any maculopathy 1.2% to 4.5%. The systemic reviewed also showed that data collected from diabetes clinic showed different result. For instance, the prevalence range for DR was 7.0% to 62.4%, PDR 0 to 6.9%, and any maculopathy 1.2% to 31.1%[5].

The prevalence of DR in Sudan was estimated to be around 17.2% in 1991[6]. Another study carried in outpatient of 3 general hospitals states in Sudan in 1995 for insulin-treated diabetic patients revealed that the prevalence of DR was 43%, nephropathy was 22% and neuropathy 37%[7]. In Australia, factors associated with DR were duration of diabetes, HbA1c, and systolic blood pressure[8]. In rural area of India, DR was not significantly associated with classic features of metabolic syndrome like blood pressure (BP), body mass index (BMI), level of education; blood concentrations of cholesterol and high-density lipoproteins. However, prevalence was significantly associated with higher age, higher blood glucose concentration and higher HbA1c concentration[9]. The frequency of DR in Cameroon was 54.1% among patients on antidiabetic medication and 73.9% among those on insulin treatment, giving an overall frequency of 57.5%[10]. While in South Africa, the prevalence rates for retinopathy, preproliferative diabetic retinopathy (PPDR) and PDR were 24.9%, 19.5% and 5.5%, respectively and risk factors were high BMI, systolic BP, being on insulin treatment, high HbA1c and the presence of neuropathy[11]. In Tanzania, the prevalence of any DR was 27.9% with background diabetic retinopathy (BDR), PPDR, PDR and maculopathy having a prevalence of 19.1%, 6.0%, 2.9% and 16.1% respectively. Risk factors identified were duration of diabetes, systolic BP and random blood sugar[12]. The prevalence of DR in Ethiopia was 41.4% with marked association with duration of diabetes, fasting blood sugar, and systemic BP[13]. The prevalence in Kenya was 35.9% and DR was associated with younger age, male sex, duration and control of diabetes, and treatment compliance[14]. Unfortunately, limited information is available about the risk factors and frequency of DR in Sudanese population. Therefore, the aim of this study is to estimate the frequency and risk factors of DR among Sudanese individuals with diabetes.

SUBJECTS AND METHODS

A cross sectional hospital based study was carried in the period between September and December 2015. The study was carried in retina clinic in Makkah Eye Complex, Riyadh branch in the capital of Khartoum city. It is a specialized eye centre where patients from all over Sudan come seeking treatment from different ethnicity and backgrounds. The participants were 316 individuals with diabetes (8.86% with type 1 diabetes and 91.14% with type 2 diabetes) attended the Retina Clinic in Makkah Eye Hospital and were willing to give their verbal consent during the study period. None of those invited to participate in this study declined. Makkah Eye Hospital is one of the few eye hospitals in Sudan that offers advanced retinal therapy in the country. Most of the patients attended this clinic were referred by medical practioners.

Data Collection The WHO stepwise approach for non-communicable diseases surveillance was used for data collection. The approach had 3 levels: a questionnaire to gather demographic information; physical measurements including anthropometric and BP and biochemical tests[15]. All diabetic patients attended the retina clinic were interviewed according to a standardized questionnaire that was filled by the investigator and this is to collect background and personal data of the patient, past medical history and common symptoms of diabetes.

Inclusion criteria included adults 18y and above. Exclusion criteria included individuals below 18y and pregnant ladies.

Anthropometric Measures Anthropometric measurements were taken using standardized techniques and calibrated equipment; measurement tape for waist circumference, measurement meter for calculating height and electronic weighing scale for weight measuring. BMI was calculated by the formula: weight in kilograms divided by height in meters squared. BMI $\leq$18.5 kg/m^2 was defined underweight, 18.5-24.9 kg/m^2 as normal, 25-29.9 kg/m^2 as overweight and >30 kg/m^2 as obesity[16].

Laboratory Measurement Blood samples were collected from each diabetic patient in Makkah Eye Complex, Retina Clinic, who was willing to participate in the study and gave his/her verbal consent. The collection was done by a skilled laboratorist in sterilized condition. Blood sample were separated in 2 vacuum tubes; Ethylene dinitrilote traacetic acid (EDTA) reagent for HbA1c (Immunoassay method using Co-bas c 111- Roche Diagnostics GmbH, Germany) and lithium reagent for lipid profile. The laboratory tests for lipid profile were carried in Makkah Eye Complex integrated laboratory using Cobas c 111 analyser was used for sample analysis.

Ophthalmic Measures The investigation was carried by a consultant ophthalmologist included slit lamp examination for iris neovascularization and dilated fundus examination using 1% tropicamide eye drop. A 90 D lens will be used to access the fundus and an indirect ophthalmoscope.

The presence of retinopathy was considered to be present if any characteristic lesion as defined in the Early Treatment Diabetic Retinopathy Study (ETDRS)[17] will be present: micro aneurisms (Mas), haemorrhages, CWS, IRMAs, hard exudates (HE), venous beading and new vessels. The severity of retinopathy was graded as no, mild, moderate, severe NPDR and PDR according to the International Clinical Diabetic

Retinopathy Disease Severity Scale and unknown if view is obscured by cataract. The presence of macular oedema and clinically significant macular oedema (CSME) was graded as described by the ETDRS.

Fundus fluorescein angiography (FFA) and optical coherence topography (OCT) document the presence of macular oedema and vitreoretinal interface.

Ethical Consideration Ethics Committee of the University Medical Science and Technology (UMST) provided the ethical clearance and approval for conducting the research. Approval from Makkah Eye complex was also taken. Verbal consent was taken from each participant before enrolment in the research, a full back ground about the research was offered to the patient, no penalty for refusal as patient had the right to withdraw at any level. Patients' information's were kept confidential and codes were assigned to participants.

Statistical Analysis Data had been cleaned, organized, coded and entered in master sheet in a personal computer and analysed using the Statistical Package for Social Science (SPSS) software program [version 21.0 computer program (SPSS, Inc., Chicago, IL, USA)]. The main variables analyzed were age, sex, BMI, blood glucose level, BP and a family history of diabetes mellitus (DM) (first degree family history), type of medication, duration of diabetes, cholesterol, triglyceride and HbA1c. Chi-squared test was used to test for significance between proportions and *t* and ANOVA tests were used to estimate associations between continuous variables. $P<0.05$ was considered statistically significant.

RESULTS

Personal and Anthropometric Characteristics of the Respondents In 316 diabetic patients enrolled in this study, 187 (59.2%) were male and 129 (40.8%) were female. The mean age of participants was 58.7±10.5 and further information can found in Table 1. The study showed that 70.9% of participants were from urban areas and approximately one third (31.7%) had higher education level. Importantly, duration of DM (72.2% of more than 10y), being on oral hypoglycaemic drugs (versus insulin), and hypertension were all risk factors for DR and with significant statistical $P<0.05$, Table 1. Complications of diabetes like diabetic foot (17.7%), history of amputation (6.7%) and CSME (47.4%) of the eyes were all risk factors with significant statistical $P<0.05$ (Table 1). Percentages of participants with history of smoking and/or alcohol intake prospectively are 64.4% and 16.8%; both habits had no statistically significant relationship with risk of DR. In this study antihypertensive medication was prescribed to 153 individuals (48%). However, only 130 (41.1%) took their antihypertensive medication regularly, while 23 individuals (6.9%) showed noncompliance.

Frequency and Risk Factors of Retinopathy Total of 261 (82.6%) were found to have DR. The percentages of the total participants with PDR were 126 (39.9%) and NPDR with 135 (42.7%). Data were cross tabulated against the various grades of DR as results are shown in Table 2; in order to determine other significant risk factors. Table 2 showed that age, BMI, cholesterol, triglyceride and HbA1c were not significant risk factors for DR in this study ($P<0.05$).

Logistic Regression to Identify Absolute Predictors of Diabetic Retinopathy We conducted stepwise logistic regression for 6 variables that were statistically significant in univariate analysis in Table 1 in order to identify absolute predictors of DR. Duration of diabetes, hypertension, and CSME were found to be absolute risk factors with *P* value of 0.007, 0.003, 0.000 respectively. Duration of DM of more than 10y have more than double risk (OR=2.8), while having hypertension triples the risk of retinopathy (OR=3.1) (Table 3).

DISCUSSION

In this study we have shown that DR rate was 82.6% and this higher than the level recorded in Sudan between 1991 and 1995 which was 17.4% and 43% respectively[6-7]. This likely due to associated increase in prevalence of diabetes in Sudan. We have recently shown that the prevalence of diabetes in urban regions of North Sudan increased to 19%[18]. Another possible factor, is an increase in specialize clinics that offer screening for DR in Sudan[19]. DR is common problem all over the globe and in particular those who live in low and middle income country[20]. For instance, the prevalence of DR in West India was 78%[21]. The global prevalence of DR was estimated to be around 34.6%[22]. It is important to recognise that there was a lot of variation in the incidence of DR across Africa. For example; the prevalence in Cameroon was in the range between 54.1% and 73.9%, South Africa 24.9%, Tanzania 27.9%, Ethiopia 41.4%, Malawai 50.1% and Keyna was 35.9%[10-14,23]. These differences may be attributed to the differences in the study setting, diagnoses techniques, measurement tools, cultural background and health seeking behaviour differences. The incidence in some European and Middle East countries were noted to be relatively low in comparison with other countries in the world. For instance, DR in Catalonia (Spain) was 12.3%, Portugal was 16.3% and Oman was 7.9%[24-26]. In UK the prevalence in Scotland was 19.3% and in Wales it was estimated for type 1 diabetes was 56% and type 2 diabetes was 30.2%[27-28]. In Scotland, retinopathy in people with type 2 diabetes at screening was associated with male sex, HbA1c, increase systolic BP and obesity[28]. In studies from five African countries (Ethiopia, Kenya, Tanzania, South Africa and Cameroon) DR was found to be associated with high BMI, systolic BP, being on insulin treatment, high HbA1c and the presence of neuropathy, duration of diabetes, random blood sugar, younger age, male sex, duration and control of diabetes, and treatment compliance[10-14]. In this study, logistic regression analysis showed that duration of diabetes, hypertension and

Table 1 Association between personal characteristics & anthropometric measurements of the respondents and development of diabetic retinopathy *n* (%)

Factors	PDR	NPDR	No retinopathy	Total	*P*
Gender					
M	80 (25.3)	77 (24.4)	30 (9.5)	187 (59.2)	0.42
F	46 (14.6)	58 (18.4)	25 (7.8)	129 (40.8)	
Residence					
Rural	33 (10.4)	47 (14.9)	12 (3.8)	92 (29.1)	0.13
Urban	93 (29.4)	88 (27.8)	43 (13.6)	224 (70.9)	
Educational level					
Illiterate + school	77 (24.1)	99 (31.4)	40 (12.8)	216 (68.3)	0.85
Higher education	49 (15.6)	36 (11.4)	15 (4.7)	100 (31.7)	
Duration of diabetes (a)					
10 or less	21 (6.6)	39 (12.3)	28 (8.9)	88 (27.8)	0.00
More than 10	105 (33.2)	96 (30.4)	27 (8.5)	228 (72.2)	
Type of medication					
Oral hypoglycaemic	46 (14.2)	66 (21.2)	33 (9.8)	145 (45.1)	0.01
Insulin	80 (25.6)	69 (21.5)	22 (6.5)	171 (54.9)	
Family history of diabetes					
Y	84 (26.7)	87 (27.6)	37 (11.7)	208 (66.0)	0.87
N	42 (13.0)	48 (15.2)	18 (5.7)	108 (34.0)	
History of alcohol intake					
Y	25 (7.6)	24 (7.6)	5 (1.6)	54 (16.8)	0.33
N	101 (32.1)	111 (35.2)	50 (15.9)	262 (83.2)	
History of smoking					
Y	38 (14.7)	53 (16.6)	22 (7.0)	113 (35.6)	0.52
N	88 (27.9)	82 (26.0)	33 (10.5)	203 (64.4)	
hypertension					
Y	71 (22.5)	65 (20.6)	16 (5.1)	152 (48.1)	0.00
N	55 (17.4)	70 (22.2)	39 (12.3)	164 (51.9)	
Diabetic foot					
Y	32 (10.1)	18 (5.7)	6 (1.9)	56 (17.7)	0.01
N	94 (29.7)	117 (37.0)	49 (15.5)	260 (82.3)	
Amputation					
Y	15 (4.8)	4 (1.3)	3 (0.4)	22 (6.7)	0.01
N	111 (35.2)	131 (41.6)	52 (16.5)	294 (93.3)	
CSME					
Y	48 (14.9)	92 (29.2)	11 (3.2)	151 (47.4)	0.00
N	78 (24.7)	43 (14.0)	44 (14.0)	165 (52.6)	

associated CSME were found to be absolute risks for DR. The high prevalence of DR in our study may be due to poor diabetes control and late referral. Several studies have shown that HbA1c is risk factor for DR[15-29]. In our study the likely reason for HbA1c was not risk factor for DR. The both groups with retinopathy and without retinopathy have poor diabetes control as HbA1c for both groups. There were 9.9% and 9.78% respectively in comparison with target treatment of 6%-7%. Despite the fact that rural residence is not a significant factor for DR, approximately one third of participants were from rural residency in this study. In rural area of India, DR was significantly associated with higher age, higher blood glucose concentration and higher HbA1c concentration[9]. The Handan Eye Study (carried in rural areas of China) showed that DR was associated with longer diabetes duration, hyperglycaemia and high BP[29]. This has important implications on public health planning in Sudan as urgent strategies are needed to monitor and treat hypertension and optimize diabetes control in individuals with diabetes in rural areas.

There is general agreement in the literature that NPDR was more prevalent than proliferative one[20]. In this study we have shown that NPDR (40.8%) was more prevalent than PDR (33.4%). Importantly, PDR (33.4%) was higher than the globally documented prevalence of 6.9% but also lower than

Table 2 ANOVA analysis to test the association between some of the expected predictors and risk of having retinopathy

Retinopathy status	No.	Mean	Std. Deviation	95% CI		*P*
				Lower bound	Upper bound	
Age (a)						
PDR	126	58.1	10.5	56.2	59.9	0.52
NPDR	135	59.5	10.3	57.8	61.3	
No retinopathy	55	58.3	11.3	55.3	61.4	
Total	316	58.7	10.5	57.6	59.9	
BMI (kg/m^2)						
PDR	126	25.8	4.5	25.0	26.6	0.30
NPDR	135	26.6	4.4	25.8	27.3	
No retinopathy	55	25.8	4.4	24.6	26.9	
Total	316	26.1	4.4	25.6	26.6	
HbA1c (%)						
PDR	126	10.2	2.8	9.7	10.8	0.60
NPDR	135	10.1	2.2	9.7	10.5	
No retinopathy	55	9.8	2.4	9.1	10.5	
Total	316	10.1	2.5	9.8	10.4	
Cholesterol (mg/dL)						
PDR	126	161.0	62.7	149.9	172.1	0.17
NPDR	135	169.5	63.7	158.5	180.4	
No retinopathy	55	151.3	55.4	136.3	166.3	
Total	316	162.9	62.01	156.0	169.8	
Triglyceride (mg/dL)						
PDR	126	147.0	101.1	128.9	164.9	0.25
NPDR	135	148.6	87.7	133.6	163.6	
No retinopathy	55	125.3	73.5	105.5	145.2	
Total	316	143.9	91.2	133.7	154.0	

Table 3 Logistic regression to identify absolute risk factors associated with increasing probability of developing diabetic retinopathy

Variables	Odd ratio	Odd ratio 95.0% CI		*P*
		Lower	Upper	
Duration of DM	2.8	1.3	6.0	0.007
Oral hypoglycemic	0.7	0.36	1.6	0.438
Being hypertensive	3.1	1.5	6.4	0.003
Diabetic foot	1.4	0.5	4.3	0.537
Amputation	1.1	0.2	6.3	0.894
Clinically significant macular edema	4.2	1.9	9.1	0.000

50.5% documented in West India[20-21]. Different metabolic factors and diseases were associated with an increased risk of DR. In different African countries, significant association was found between PDR and diabetes complications such as diabetic foot, amputation and maculopathy[10-14]. This is probably due to the association with poor glycaemic control and longer duration of diabetes. This may also explain the high prevalence of moderate PDR. Visual loss in DR was noted with an increase with age, in this study CSME was an absolute risk factor for DR[30]. The prevalence of CSME in Saudia Arabia was noted to be around 7.2% and DR was associated with similar risk factors found in our study (longer duration of diabetes, poorly controlled diabetes, hypertension and insulin use)[31].

Among this study participants; 72.2% were found having diabetes for more than 10y , and 27.8% had a diabetes for less than 10y. This may explain in part, in this study duration of diabetes was strongly significant risk factor for retinopathy and this was supported in most of the studies carried about DR and suggestions that probably diabetes duration is the strongest predictor for DR development and progression[32-33]. This is likely due to the affects of the small blood vessels leading to the diabetes microvascular complications[34]. In this study, 53.2% of study participants were on insulin therapy which was found significantly associated with retinopathy development. It worth mentioning that, insulin therapy represented advancement on diabetes treatment and resulted in better glycaemic control, however insulin therapy may be started late or it may have failed in preventing long term complication of diabetes[35]. The chronic hyperglycaemia associated with DR impairs the regulation of retinal perfusion which in turn leads to increased susceptibility to injury from systemic hypertension and this

was clearly demonstrated in this study as 48.1% of diabetic patients were found hypertensive and the effect of hypertension on progression of retinopathy was highly significant. Moreover this strongly supports what is documented in the literature about DM and hypertension combination role in multiplying the risk of macrovascular and microvascular disease[36]. This study is not without limitations. The study design was a cross-sectional study, so we could not take account of the temporal relationship between potential risk factors and outcomes. Another limitation is short duration of the study. Despite these factors, we believe that this study is novel and its findings reflect the trend of rising frequency of DR in developing countries. Frequency of DR in this study was very high among individual with diabetes. Duration of diabetes, insulin use and hypertension, diabetic foot and amputations are significant associated factors for DR. More population based studies and surveillance should be carried out to address the actual magnitude of the problem. Importantly, awareness and education programs on DR should be highly encouraged. Early screening programs are of great value in containing the increasing incidence of DR.

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