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Clinical characteristics and associated factors of diabetic retinopathy in Sudanese patients

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Background: Diabetic retinopathy (DR) is a leading cause of vision loss and preventable blindness, particularly in middle- and high-income countries.

Aim: This study aimed to assess the characteristics and associated factors of DR in Sudanese patients with type 2 diabetes mellitus (DM).

Setting: A cross-sectional hospital-based study included 119 patients with type 2 DM was conducted at EL-Walidain Eye Hospital, Khartoum, Sudan, from February 2021 to May 2021.

Methods: A non-mydriatic digital fundus camera was used for fundus photography, and Scottish Diabetic Retinopathy Grading Scheme was used for the final classification of DR.

Results: Females comprised 53.8% of patients, mean age of 58.8 ± 8.5 years. Uncontrolled DM was found in 37.8% with a mean duration of 10.5 ± 4.8 years. Myopia was the most common refractive error found in 57.8% of the uncontrolled group, followed by emmetropia (17.8%). Whereas in the controlled group, 47.3% were hyperopic and 39.2% were myopic. Maculopathy grade M1 was found to be 37.8% in the uncontrolled group and 18.9% in the controlled group, with no significant difference (p = 0.361). Conversely, the difference in retinopathy between the two groups was statistically significant (p = 0.043).

Conclusion: Decreased vision and increased retinopathy were associated with an increase in patients' age. More widespread diabetes awareness and screening programmes to improve diabetes management and control in Sudan and other developing countries.

Contribution: This study observed maculopathy grade M1 and myopia were more common in uncontrolled DM, and vision function was inversely correlated with age ($p < 0.05$).

Keywords: diabetes mellitus; retinopathy; maculopathy; diabetic retinopathy; Sudan.

Introduction

Diabetes mellitus (DM) is a metabolic disorder that causes high blood sugar levels because of problems with insulin: a hormone that regulates blood sugar.[1,2] There are two main types of DM: type 1 and type 2. Type 1 DM, commonly called juvenile-onset or insulin-dependent DM, usually starts in childhood. Whereas Type 2, known as adult-onset or non-insulin-dependent DM, typically develops after the age of 40 years and becomes more common with the advancement of age.[2,3] Type 2 DM is more prevalent and often associated with lifestyle factors like diet and physical activity. According to the World Health Organization (WHO), around 462 million people worldwide have DM, most of them living in low- and middle-income countries where access to healthcare is limited.[4,5,6,7] Sub-Saharan Africa experiencing a diabetes epidemic that leads to considerable health problems, including preventable visual loss caused by diabetic retinopathy (DR).[8]

Diabetic retinopathy is an eye disease that causes damage to the retina and is considered as the primary cause of vision loss and avoidable blindness among adults aged 20–74 years, especially in middle- and high-income countries.[9] In 2020, it was estimated that about 103.12 million adults worldwide suffer from DR, 28.54 million people have vision-threatening DR, and 18.83 million persons have clinically significant macular oedema. By 2045, these numbers are expected to increase by approximately 30% – 50%; with 160.50 million persons predicted to suffer from DR, 44.82 million people will have vision-threatening DR, and 28.61 million will have macular

oedema.[10,11,12,13,14,15] A study was conducted to assess the prevalence and incidence of DR and diabetic maculopathy in African countries. It was reported that prevalence range in patients with diabetes for DR was 30.2% – 31.6%, proliferative DR 0.9% – 1.3% and any maculopathy 1.2% – 4.5%.[16] Diabetic retinopathy has two stages: non-proliferative diabetic retinopathy (NPDR) and proliferative diabetic retinopathy (PDR). The NPDR is the initial stage where small blood vessels in the retina leak fluid or blood, leading to retinal enlargement and the formation of deposits called exudates.[8,9,10] Whereas the PDR is the most advanced stage of DR, in this condition, new blood vessels begin to grow on the surface of the retina, but they are fragile and can bleed into the vitreous, resulting in severe vision loss and even blindness.[11,12]

The grading system for DR helps eye care professionals to monitor and manage the progression of the condition, enabling timely intervention to preserve vision. It involves various stages, ranging from mild to severe. The widely used grading system is the Early Treatment Diabetic Retinopathy Study (ETDRS) classification, as follows: The stages include no apparent retinopathy (NDR); this stage occurs in the early years of DM and shows no visible signs of DR. In mild NPDR, microaneurysms appear in the retina's blood vessels, but vision is usually not significantly affected. In moderate NPDR, alongside microaneurysms, there is a greater presence of haemorrhage exudates in the retina, and vision may be mildly affected. Whereas in severe NPDR, this stage reveals more pronounced changes, including significant haemorrhages and other signs of blood vessel damage, and vision is more likely to be affected.[12,17,18] Conversely, the Scottish Grading protocol is used to grade the severity of retinopathy and maculopathy. Retinopathy is graded from R0 to R4, while maculopathy has separate grades from M0 to M2. R6 is a grade for poor-quality images that cannot be graded. If patients have technical failures during photography, they need to undergo further screening using slit lamp biomicroscopy.[19]

Previous studies[19,20,21] reported that detecting DR through screening requires an approximately 30-min examination of the ocular fundus, which helps to identify the condition early on and improve treatment outcomes. Early management delays the consequences that lead to vision impairment or lessens the likelihood of worsening the impairment.[19,20,21] The management of DR involves medical and surgical interventions. Treatment options include controlling blood sugar levels and using anti-vascular endothelial growth factor (VEGF) drugs such as ranibizumab or aflibercept, which are injected into the eye to treat diabetic macular oedema and PDR.[21,22] As well as other medical modalities used to manage DR, such as statins, renal compromise, the use of angiotensin-converting enzyme (ACE) inhibitors or Ag II inhibitors. This study was conducted to assess the clinical characteristics and associated factors of DR in Sudanese patients attending a not-for-profit tertiary eye care centre.

Methods

Study design

This was a cross-sectional hospital-based study conducted at the retina clinic of EL-Walidain Eye Charity Hospital in Khartoum city in the period from February to May 2021. EL-Walidain Eye Charity Hospital is a specialised eye centre that treats patients from various regions and backgrounds across Sudan.

Sample

The study included 119 patients who were already diagnosed with type 2 diabetes. They were selected from patients who came to the hospital seeking eye care, and their ages ranged from 40 years to 75 years. The sample included 64 females and 55 males from different regions of Sudan, who attended the retina clinic in El-Walidain Charity Eye Hospital and were willing to participate in the study.

Inclusion criteria

The study included adults aged 40–75 years old with type 2 DM as the inclusion criteria. Individuals below 40 years of age and pregnant women were excluded from the study, and any person who had previous eye surgery was also not included in the study.

Data collection procedures

For all diabetic patients who visited the retina clinic, their demographic information was collected. The investigator asked the patients to provide background and personal information, as well as the patients' medical history and common diabetes symptoms. This included a review of both the ocular and systemic status of the patient, along with the diabetic history, including duration of diabetes, blood sugar control, medical status and family history. Participants were subjected to comprehensive ocular examinations. Slit lamp biomicroscopy was used to examine the anterior segment of the eye. Visual acuity (VA), best-corrected visual acuity (BCVA) and pinhole were estimated by Snellen's E-test type. The refractive status of the eye was evaluated by an autorefractometer (Nidek, Gamagori, Japan). Finally, for the patient's posterior segment examination, the study used seven-field fundus photography. The seven fields from 1 to 7 are the optic disc, macula, temporal to the macula, superior temporal, inferior temporal, superior nasal and inferior nasal, respectively. The VISUCAM® 500 (Zeiss GMBH, Jena); a non-mydriatic digital fundus camera, which allows taking photographs through pupils as small as 3.3 mm, was used for imaging and evaluating the retina thoroughly for the presence of DR. Based on the Scottish Diabetic Retinopathy Grading Scheme (SDRGS)[19] screening and referral programme for DR that was adapted for use in Sudan, fundus images were analysed, diabetic and macular retinopathy were graded and action was taken as seen in Table 1.

Microaneurysms were recorded by viewing them in colour and red free. Intraretinal microvascular abnormality (IRMA)

was recorded when visible on colour images without enlarging the image area.

Data analysis

Descriptive and comparative statistical analyses were performed using Statistical Package for the Social Sciences (SPSS) for Windows version 24 (SPPS Inc., Chicago, IL, United States). Data were reported as mean ± standard deviation (s.d.). Pearson's correlation was used to find the relationship between dependent and independent variables among the study population. A p-value of < 0.05 was considered to be statistically significant with a 95% confidence level (CL).

Ethical considerations

Ethical permission for the study was obtained from the Ethics Committee of Al-Neelain University (approval No. 21-01-12). The study was conducted according to the Declaration of Helsinki guidelines. Participants in the research provided verbal consent after receiving detailed information about the study. They had the right to withdraw at any stage without facing any penalties. Patients' confidentiality was maintained by assigning codes to the participants' information.

Results

Demographic information

This study included 119 patients with DM type 2 whose ages ranged from 40 years to 75 years, with a mean age of 58.8 ± 8.5 years. About 55 of them were males (31 controlled DM type 2 and 24 with uncontrolled DM type 2), and 64 were females (43 controlled DM type 2 and 21 with uncontrolled DM type 2). Diabetes mellitus duration was significantly different ($p < 0.001$) between the controlled group, whose duration ranged from 1 years to 19 years with a mean of 7.1 ± 4.5 years and the uncontrolled group, whose duration ranged from 1 years to 20 years with a mean of 10.5 ± 4.8 years. Mean and s.d. of blood sugar level using cumulative haemoglobin HbA1C for controlled and uncontrolled MD were 5.93 ± 1.1 and 7.89 ± 2.1, respectively, $p = 0.0001$.

Distribution of visual acuity and refractive error among participants

Refractive error among the participants showed the following: 47.3%, 12.2%, 39.2% and 1.4% of the controlled group were hyperopes, myopes, emmetropes and of no fundus reflex, respectively. While in the uncontrolled group, 13.3%, 57.18%, 17.8% and 11.1% were hyperopes, myopes, emmetropes and had no fundus reflex, respectively. Paired samples T test showed non-significant differences between unaided VA and BCVA of right and left eyes for both controlled and uncontrolled eyes ($p > 0.05$), as shown in Table 2. Unaided VA was found to be strongly inversely correlated with age ($p < 0.05$), while BCVA was found to be weakly inversely correlated with age ($p > 0.05$). Table 3 shows the distribution of methods used to control DM among participants.

Maculopathy grading among the participants

Regarding maculopathy, most of the patients with controlled DM, 58 (78.4%), had no maculopathy; only 14 (18.9%) had grade M1 of maculopathy. While in the patients with

TABLE 2: Unaided visual acuity and best-corrected visual acuity among the participants.

Group	Visual acuity	*n*	Mean ± s.d.	*p*
Controlled	Unaided VA RE	74	0.55 ± 0.34	0.194
	Unaided VA LE	74	0.52 ± 0.34	
	BCVA RE	74	0.54 ± 0.35	0.375
	BCVA LE	74	0.58 ± 0.34	
Uncontrolled	Unaided VA RE	45	0.31 ± 0.30	0.152
	Unaided VA LE	45	0.32 ± 0.30	
	BCVA RE	45	0.42 ± 0.35	0.437
	BCVA LE	45	0.4745 ± 0.36	

Note: Visual acuity is assessed by the Snellen chart by decimal fraction.

VA, visual acuity; BCVA, best-corrected visual acuity; RE, refractive error; LE, left eye; s.d., standard deviation.

TABLE 3: Distribution of patients according to control methods.

Method of control	Frequency (*n*)	%
Diet and exercise	15	12.61
Medications	46	38.66
Diet and exercise, medication	13	10.92
Irregular diet and exercise	10	8.4
Nothing	35	29.41
Total	**119**	**100**

TABLE 1: Grading, features and action taken for diabetic retinopathy.

Grade	Features	Action taken
RO	Normal retina: isolated cotton wool spots	Annual screening
R1	Mild background diabetic retinopathy (DR): cotton wool spots (CWS), microaneurysm(s), venous loop haemorrhage(s), ± any exudate.	Annual screening
R2	Moderate background DR: venous beading, multiple haemorrhages, venous loop, intraretinal microvascular abnormality (IRMA), round or blot haemorrhages and CWS.	Refer to retina consultant
R3	Severe non-proliferative or pre-proliferative new vessels on disc (NVD), IRMA, and new vessels elsewhere (NVE), pre-retinal or vitreous haemorrhages, pre-retinal fibrosis ± retinal detachment.	Refer to retina consultant
R4	Proliferative DR, NVD, NVE, pre-retinal or vitreous haemorrhages, pre-retinal fibrosis ± tractional retinal detachment.	Refer to retina consultant
MO	Normal macula	Annual screening
M1	Macular oedema exudates within one-disc diameter (DD) of the centre of the fovea. Group of exudates within the macula: any microaneurysm or haemorrhage within one DD of the centre of the fovea only if associated with a best visual acuity of ≤ 6/12.	6 months screening
P0	No evidence of previous photocoagulation.	-
P	Focal and/or grid to macula or peripheral scatter.	-
U	Un-gradable and/or unobtainable media opacity.	Refer to retina consultant

Source: Zachariah S, Wykes W, Yorston D. Grading diabetic retinopathy (DR) using the Scottish grading protocol. Community Eye Health. 2015;28(92):72

TABLE 4: Distribution of maculopathy grading among the participants.

Control	Right eye maculopathy		Left eye maculopathy		*p*
	Frequency	Percentage	Frequency	Percentage	
Controlled					
U	2	2.7	2	2.7	0.361
M0	58	78.4	57	77.0	-
M1	14	18.9	15	20.3	-
Total	74	100.0	74	100.0	
Uncontrolled					
U	5	11.1	5	11.1	-
M0	23	51.1	24	53.3	-
M1	17	37.8	16	35.6	-
Total	45	100.0	45	100.0	-

M0, no maculopathy; M1, exudates within 1 disc diameter (DD), any microaneurysm or haemorrhage within 1 DD of the centre of the fovea only if associated with best-corrected visual acuity (BCVA) of ≤ 6/12; U, not classified.

TABLE 5: Distribution of retinopathy grading among the participants.

Group	Grading	Right eye retinopathy		Left eye retinopathy		*p*
		Frequency	Percentage	Frequency	Percentage	
Controlled	U	2	2.7	2	2.7	0.043
	R0	29	39.2	29	39.2	-
	R1	20	27.0	20	27.0	-
	R2	13	17.6	13	17.6	-
	R3	8	10.8	8	10.8	-
	R4	2	2.7	2	2.7	-
	Total	74	100.0	74	100.0	-
Uncontrolled	U	5	11.1	5	11.1	-
	R0	7	15.6	7	15.6	-
	R1	10	22.2	10	22.2	-
	R2	9	20.0	9	20.0	-
	R3	9	20.0	9	20.0	-
	R4	5	11.1	5	11.1	-
	Total	45	100.0	45	100.0	-

R0, no diabetic retinopathy disease; R1, mild background diabetic retinopathy; R2, moderate background diabetic retinopathy; R3, severe non-proliferative or pre-proliferative diabetic retinopathy; R4, proliferative diabetic retinopathy; U, not classified.

uncontrolled DM, no maculopathy was found in 23 (51.1%), and grade M1 maculopathy was found in 17 (37.2%). Maculopathy among the patients with controlled and uncontrolled DM was statistically not significant ($p = 0.361$), as shown in Table 4.

Retinopathy grading among the participants

Retinopathy grading among the participants with controlled DM showed the following: 20 (27%) had mild retinopathy, 13 (17.6%) had moderate retinopathy and 8 (10.8%) had severe retinopathy. Whereas in the uncontrolled group, 10 (22.2%) had mild retinopathy, 9 (20.0%) had moderate retinopathy. Nine (20.0%) had severe retinopathy, and 5 (11.1%) had proliferative retinopathy. The difference in retinopathy between patients with controlled and uncontrolled DM was statistically significant ($p = 0.043$), as shown in Table 5. Table 6 shows the distribution of photocoagulation among participants.

Discussion

Diabetic retinopathy is a common eye disorder worldwide, especially among people living in low- and middle-income countries.[9] If left unmanaged, DR may lead to visual impairment and blindness.[9] It is crucial to acknowledge that

TABLE 6: Distribution of photocoagulation in the participants.

Group	Photocoagulation	Frequency	Percentage	*p*
Controlled	U	2	2.7	0.28
	P0	69	93.2	-
	P	3	4.1	-
	Total	74	100.0	-
Uncontrolled	P0	42	93.3	-
	P	3	6.7	-
	Total	45	100.0	-

Note: The Whitney test between controlled and uncontrolled DM groups in the right and left eyes showed non-significant statistical differences ($p = 0.28$) in terms of maculopathy and photocoagulation.

P0, no evidence of photocoagulation; P, evidence of previous of photocoagulation; U, not classified.

there are substantial ethnic-based differences in the clinical features and contributing factors of DR, with higher prevalence observed across people of African descent.[23] Thus, our present study was conducted to assess the clinical characteristics and associated factors of DR in Sudanese patients with DM type 2 seeking eye care.

An earlier study showed that decreased vision function in DR was associated with an increase in patients' age.[23] This study revealed that the unaided VA and BCVA were strongly inversely correlated with age. Furthermore, the study showed that increased retinopathy was associated with an increase in patients' age. Our finding is consistent with a previous study,[24] which reported that DR showed a strong correlation with factors such as older age, elevated blood glucose levels and increased HbA1c levels. This study showed that considerable numbers of patients with DM remain without any method of control, and with a long duration of diabetes, some extending to 20 years. This study found that the duration of DM was a significant influential risk factor for the development of retinopathy. This finding is consistent with previous studies,[25,26] suggesting that the duration of DM is likely the most powerful predictor for the development and progression of DR. These agreed with the Handan Eye Study conducted in rural areas of China, which revealed that DR was linked to a longer duration of DM, high blood sugar levels and hypertension.[27] These findings hold significant importance for public health planning in Sudan, highlighting the need for urgent strategies to monitor and manage systematic disorders as well as optimise diabetes control among individuals living with diabetes in rural regions. There is a lack of healthcare facilities in these regions. This study found that myopia was more common in uncontrolled DM compared with controlled groups. This finding highlighted the need for eye care professionals to ensure that DM is controlled or at a normal level when prescribing the correction of uncorrected refractive for patients with DM.

In this study, only 11.1% had PDR, all of them from uncontrolled DM groups. This agreed with the existing literature, which showed that NPDR was more prevalent than proliferative one.[28,29] Various metabolic factors and diseases were identified as risk factors for DR. In several African countries, a notable connection was observed between PDR and complications of diabetes, including

diabetic foot, amputation and maculopathy.[29,30,31] This highlights the need for early screening, which would lead to early diagnosis and management.[32] It has been observed that early assessment and management would reduce the risk of complications that lead to visual impairment.[19,20,21] Nevertheless, because of scarcity of ophthalmologists in Africa,[32] inefficient referrals may hinder the efforts of early detection through screening. It has been suggested that remote screening and tele-diagnosis can alleviate the pressure on the healthcare system and fill the gap.[33] This study did not investigate the role of early detection through screenings or the role of tele-diagnosis. However, it would be of interest to identify these factors in the future as the opportunity for tele-diagnosis in DR is promising for developing countries.[34]

This study has some limitations. As a result of the cross-sectional study design, the temporal relationship between potential risk factors and outcomes could not be considered. In addition, the study had a short duration, which did not allow for further patient recruitment. Furthermore, the study included a small number of patients with DM all of them were type 2 DM. Despite these factors, we believe that this study provides useful information about the clinical characteristics and associated factors of DR among Sudanese patients with type 2 DM who seek eye care.

Conclusion

The study found considerable numbers of patients with DM remain without any method of control and with a long duration of diabetes, some extending to 20 years, which reveals the importance of awareness of diabetic control and regular screening of diabetic patients to prevent visual loss and reduce the rate of DR progression. Maculopathy grade M1 and myopia was more common in uncontrolled DM compared with controlled groups. Decreased vision and increased retinopathy were associated with an increase in patients' age. These facts highlight the need for urgent public health strategies in Sudan to monitor and manage systematic disorders as well as optimise diabetes control.

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Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

Authors' contributions

N.M.M. and S.H.A was the project leader who was responsible for the experimental and project design, Y.G., A.M.E. made conceptual contributions and provided guidance for the study. N.M.M. and S.H.A. were responsible for the writing of this article with input and edits from Y.G. and A.M.E.

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Data availability

Data supporting the findings of this study are available from the corresponding author, N.M.M., on request.

Disclaimer

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