


BMJ Open Burden of diabetic macular oedema and its associated factors among adult patients with diabetes attending comprehensive specialised hospitals in Northwest Ethiopia, 2023: a multicentre cross-sectional study

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ABSTRACT

Objective This study aimed to assess the prevalence of diabetic macular oedema and its associated factors among adult patients with diabetes attending comprehensive specialised hospitals in Northwest Ethiopia in 2023.

Design An institution-based, cross-sectional study.

Setting The study was conducted at the University of Gondar, Felege Hiwot and Debre Markos comprehensive specialised hospitals in Northwest Ethiopia from 8 May to 15 June 2023.

Participants This study was conducted on 890 adult patients with diabetes selected using a systematic random sampling technique.

Outcome measures Participants with diabetic macular oedema were assessed using slit lamp biomicroscopy with a +90 dioptre Volk lens. Blood glucose levels were measured by fasting blood sugar tests. Data were collected through physical examination, review of medical records and face-to-face interview.

Results Among a total of 890 study participants, the prevalence of diabetic macular oedema was 25.8% (95% CI 23.1 to 28.8). Peripheral neuropathy (adjusted OR (AOR)=3.02, 95% CI 1.76 to 5.29), hypertension (AOR=1.98, 95% CI 1.24 to 3.17), poor blood glucose control (AOR=5.06, 95% CI 2.95 to 8.67), obesity (AOR=5.03, 95% CI 2.50 to 10.13), longer duration of diabetes mellitus (AOR=3.78, 95% CI 2.21 to 6.24) and poor adherence to diabetic medication (AOR=2.06, 95% CI 1.32 to 3.28) were significantly associated with diabetic macular oedema.

Conclusion In Northwest Ethiopia, a quarter of patients with diabetes were found to have diabetic macular oedema. Factors such as peripheral neuropathy, hypertension, poor blood glucose levels, obesity, long duration of diabetes mellitus and poor adherence to diabetic medications were significantly associated with diabetic macular oedema. Improvement of glucose control and exercise for optimal body weight maintenance are recommended to prevent the development of diabetic macular oedema.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The strengths include the study's better representation of the population.
- ⇒ This study was conducted on a diverse study population across a wide geographical area.
- ⇒ The study was not able to show cause and effect relationships.
- ⇒ We were unable to obtain complete information regarding lipid profile due to lack of accessibility in the study area.
- ⇒ Limited access to advanced diagnostic tools such as ocular coherence tomography hindered our ability to use them in the study.

INTRODUCTION

Diabetes mellitus (DM) is an uncontrolled high blood glucose level within the blood vessels resulting from deficiency in insulin or resistance to insulin. The most common retinal consequence of DM is diabetic retinopathy (DR), which leads to impaired vision.¹ DR is a serious eye condition that damages the small blood vessels in the retina due to prolonged high blood glucose levels.² Among the DR complications, diabetic macular oedema (DMO) is one of the most common causes of vision loss. It is characterised by an accumulation of fluid around and within the macula caused by leakage of blood vessels due to elevated blood glucose.³

Globally, 93 million people suffer from DR, of whom 21 million have DMO and 17 million have proliferative diabetic retinopathy (PDR).⁴ This translates to a prevalence rate of 35.4% DR, 7.4% DMO and 7.2% PDR worldwide.⁴⁻⁶ Among the DR complications, DMO is the most common cause of vision

loss, with prevalence ranging from 3.8% to 11.1% in Western nations⁷⁻⁹ and from 8.0% to 33.0% in Africa.¹⁰⁻¹² Specifically in Ethiopia, it is observed to vary from 5.7% to 26.3%.^{13 14} This evidence suggests that the burden of DMO is relatively higher in developing nations.¹⁵ Furthermore, Ethiopia is reported as one of the nation's getting higher rates of DMO.¹³

Despite advancements in diagnosis and treatment, DMO continues to be the primary cause of visual impairment (VI) globally, posing severe public health concerns.¹⁶ In comparison with individuals without DMO, those with DMO are faced with a huge burden both at the individual and community level, as well as at the healthcare system level. Increased direct and indirect financial burden, increased utilisation of healthcare services and decline in quality of life have been considered among the huge burdens suffered by the patients.¹⁷

There are several factors associated with DMO, including age, sex, body mass index (BMI), place of residence, pregnancy, hypertension, high blood pressure, poor blood glucose control, longer duration of DM, higher cholesterol level, type 2DM, insulin and family history of DM.^{4 6 13 18-23}

To reduce the impact of DMO and its associated complications, it is crucial to implement a variety of interventions, including education, disease prevention strategies, dietary improvements, increased physical activity and regular screenings. A strong focus on education and disease prevention, especially through diabetic eye screening programmes, is vital for early detection and management of DMO.¹⁷

Despite the implementation of various interventions, DMO remains a significant health concern, particularly in Ethiopia. However, research on DMO in this region is limited. Conducting studies on DMO and its associated factors is crucial to provide targeted interventions that are based on modifiable predictors. Therefore, this study aimed to determine the prevalence of DMO and its associated factors among adult patients with diabetes attending comprehensive specialised hospitals in North-west Ethiopia.

METHODS

Study design, area and period

A multicentre cross-sectional study was carried out in three (Debre Markos, Felege Hiwot and University of Gondar) of five diabetic care clinics of the comprehensive specialised hospitals found in Northwest Ethiopia from 8 May to 15 June 2023. These comprehensive specialised hospitals were selected randomly from the five that have separate adult diabetic care clinics and eye care clinics. General practitioners, internists, nurses and residents staff each diabetic clinic of the hospitals. These comprehensive specialised hospitals have limited resources while being the last option in the referral hierarchy. Only Volk lens funduscopy and other manual approaches have been used for diagnostic purposes in the eye care clinics, which

are particularly lacking in sophisticated and essential diagnostic tools such as fundus cameras and ocular coherence tomography (OCT).

Source population

The source population included all adult patients with diabetes attending the selected comprehensive specialised hospital diabetic clinics.

Study population

The study population included all adult patients with diabetes attending the selected comprehensive specialised hospital diabetic clinics and presented during the data collection period.

Eligibility criteria

All patients aged 18 years and above, medically diagnosed with DM and with adequate visualisation of the posterior segment of an eye were included in this study. However, patients with media opacity that obscured the posterior segment, such as dense corneal opacity, mature cataract and marked vitreous opacity, and patients with acute illness due to unreliable response were kindly excluded from the study.

Sample size determination

The sample size was determined using a single population formula:

$$n = \frac{(Z_{\alpha/2})^2 \times P(1-P)}{d^2} = \frac{(1.96)^2 \times 0.17(1-0.17)}{0.02^2} = 603$$

where n is the sample size; Z is the value of z statistics at 95% confidence level, which is 1.96; P is the expected proportion of DMO of 0.17, which was taken from a study done in Gondar, Ethiopia¹³; and d is the margin of error, which is 2%.

The calculated sample size was determined to be 603. Finally, taking into account a design effect of 1.5 and a 10% non-response rate, the final sample size was confirmed to be 995.

Sampling technique and procedures

At the University of Gondar, Felege Hiwot and Debre Markos comprehensive specialised hospitals, approximately 2254 new and follow-up patients with DM receive services within a 5-week period. At each hospital, the average number of patients per 5-week period was 675, 854 and 725, respectively (figure 1). Besides, the overall sample size was 995. The study participants were selected using a systematic random sampling technique. The sampling interval (K) was calculated by dividing the expected number of patients with diabetes who came to the diabetic clinic in the previous year in the same month of the current data collection period by the required sample size.

$$K = \frac{N}{n} = \frac{2254}{995} = 2.26 \approx 2$$

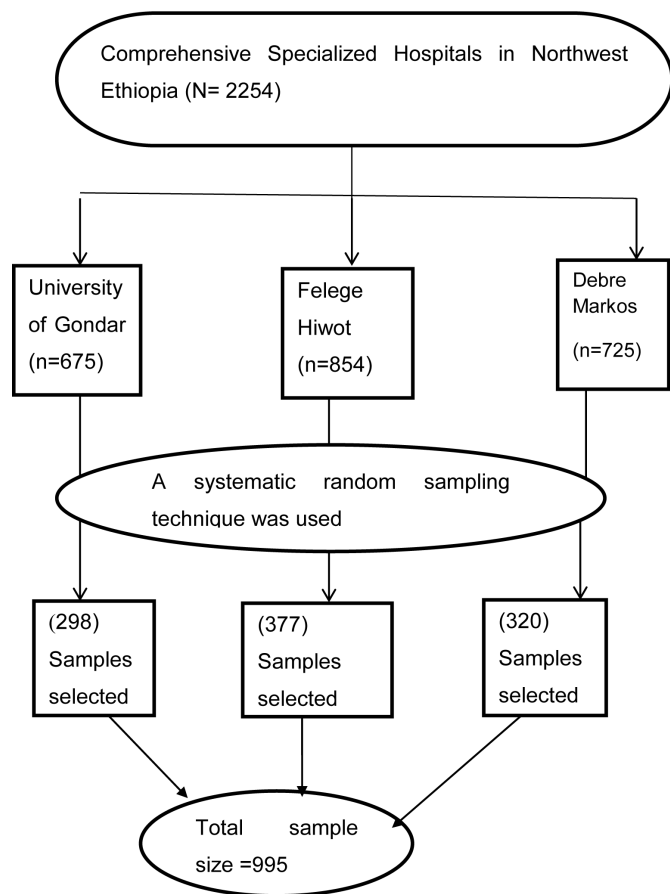


Figure 1 The sampling procedure used to select the participants of the study conducted in Northwest Ethiopia.

We used the lottery method to draw the first sample of the first two study subjects and continued with every other participant.

Variables

- ▶ Dependent variable: DMO.
- ▶ Independent variables.
 - Sociodemographic variables: sex, age, residence, marital status, educational status, occupational status, average monthly family income and health insurance.
 - Clinical variables: type of DM, fasting blood glucose status, blood pressure, mode of treatment, BMI, duration of DM, family history of DM, adherence to DM medications, awareness towards DM, eye check-up practice and VI.
 - Ocular and systemic comorbidities: cataract, glaucoma, DR, diabetic peripheral neuropathy, diabetic nephropathy, chronic foot ulcer, hypertension and chronic kidney disease.

Operational definition

- ▶ Diabetic macular oedema: According to the National Health and Nutrition Examination Survey Digital Grading Protocol, DMO is the accumulation of fluid in the macula, retinal thickening as well as cystic spaces in at least two consecutive rasters.⁷

- ▶ Clinically significant macular oedema: According to the Early Treatment Diabetic Retinopathy Study grading criteria, the presence of retinal thickening at or within 500 μm of the centre of the macula or hard exudates at or within 500 μm of the centre of the macula was defined as clinically significant macular oedema in this study.¹⁴
- ▶ Fasting blood glucose status: Study subjects with fasting blood glucose level of 130 mg/dL and below measured during data collection were considered as individuals with good controlled blood glucose. On the other hand, having more than 130 mg/dL fasting glucose level measured during the data collection was considered as poorly controlled blood glucose.²⁴
- ▶ Visual impairment: Study participants were considered visually impaired if their presenting distance visual acuity (PVA) was less than 6/12 in the better eye.¹³
 - No VI: 6/12 or better PVA in the better eye.
 - Mild VI: PVA worse than 6/12–6/18 in the better eye.
 - Moderate VI: PVA worse than 6/18–6/60 in the better eye.
 - Severe VI: PVA worse than 6/60 to count figure at 1 m in the better eye.
 - Blind: PVA worse than count finger at 1 m.
- ▶ Adult: Individuals aged 18 years or older were considered adults.²⁵
- ▶ Body mass index: BMI was calculated by dividing the weight in kilograms by the height in metre square, according to the results of the measurement at the time of data collection.²⁶
 - Underweight: BMI <18.50 kg/m².
 - Normal: BMI 18.50–24.99 kg/m².
 - Overweight: BMI 25.00–29.99 kg/m².
 - Obesity: BMI \geq 30 kg/m².
- ▶ Glaucoma: Glaucoma diagnosis involved the vertical cup to disc ratio (VCDR), other glaucomatous fundus changes and intraocular pressure (IOP). An eye was diagnosed as having glaucoma when it has a VCDR of >0.7, along with other glaucomatous fundus changes such as notching of the vessels emerging from the cup, splinter haemorrhage, thinning of the neuroretinal rim and nerve fibre layer defect in an eye with a VCDR of >0.5 and IOP greater than 21 mm Hg.²⁷
- ▶ Diabetic retinopathy: DR is diagnosed as the presence of microaneurysms, haemorrhages, exudation, cotton wool spots and/or new vessels in the fundus of at least one of the patient's eyes.²⁸
- ▶ Hypertension: Individuals with systolic and/or diastolic blood pressure above 140/90 mm Hg measured during the data collection period or taking antihypertensive medications were considered as patients with hypertension, whereas subjects with both systolic and diastolic blood pressure below 140/90 mm Hg during the data collection period and with no known history of hypertension were deemed free from hypertension.²⁹

- ▶ Peripheral neuropathy: A known history of peripheral neuropathy or the presence of varying degrees of symptoms such as numbness, hyperalgesia, tingling, burning sensation, allodynia, weakness of limbs, aching and pain exacerbated at night-time was the confirmatory criteria for diagnosing peripheral neuropathy.³⁰
- ▶ Diabetic nephropathy: Study participants having known diabetic nephropathy or confirmed presence of >0.5 g proteinuria per 24 hours.³¹
- ▶ Eye check-up practice: Individuals with a history of eye exams over the previous 12 months were classified as having good eye check-up practices, whereas those without a history of eye exams were classified as having poor eye check-up practices.³²
- ▶ Adherence to DM medications: Participants in the study were deemed to have poor adherence to DM medications if their response to the 7-point treatment adherence questions fell below the median value. On the other hand, participants were deemed to have high adherence to DM treatment if their scores were above or equivalent to the median.³³

Data collection tool and procedure

The data were collected by three senior optometrists and another three ophthalmologists using the electronic device KoboToolbox V.2022.4.4. The data were collected through interviews, ocular and physical examinations, and chart review using a pretested, semistructured questionnaire consisting of sociodemographic status, clinical characteristics and systemic and ocular comorbidities.

First, the PVA of the study subject was evaluated using a reduced Snellen visual acuity chart at a 3 m distance, followed by height and weight measurement using a stadiometer. The patient's IOP was then measured using a Goldmann applanation tonometer, and conventional slit lamp biomicroscopy (Haag-Streit, Bern, Switzerland) was considered for anterior segment examination. For the study subjects indicated for funduscopy, the optometrist in charge of data collection instilled a drop of 1% tropicamide eye-drop to prepare the subjects for funduscopy to be done by a senior ophthalmologist. After the posterior segment of an eye has been evaluated using a slit lamp biomicroscope and +90.00 dioptre Volk lens, the ophthalmologist then decided the status of DMO.

After conducting physical and clinical examinations, participants were interviewed in person to gather socio-demographic information and relevant clinical data. Each participant's medical records were also reviewed to extract clinical information such as hypertension, peripheral neuropathy, nephropathy, diabetic foot ulcers, type of DM, blood pressure readings and fasting blood glucose levels.

Data quality assurance

The internal validity of the study was assessed through a pretest conducted on 5% of the sample size at Debarik General Hospital. Based on the pretest results, necessary

adjustments were made. To ensure consistency in the questionnaire, it was first translated into Amharic (the local language) and then translated back into English by language experts. This careful translation process was essential to maintain the integrity of the questionnaire. To oversee the data collection process, skilled data collectors were supervised daily by a supervisor. Before data analysis, the principal investigator thoroughly reviewed the entered data to ensure clarity, completeness and accuracy.

Statistical analysis

After collecting the data, they were then exported to Stata V.14 for checking, cleaning and analysis. Descriptive statistics were presented using proportions, frequencies and ratios. Additionally, summary measures such as median and IQR were calculated using the same statistical software. To assess the relationship between the predictors and the dependent variables, a bivariable logistic regression analysis was performed. In the multivariable logistic regression, a p value of less than 0.05, along with 95% CI, was considered as a cut point to determine significant associations with DMO. The model's fitness was evaluated using the Hosmer and Lemeshow goodness-of-fit test, which produced a p value of 0.79.

Patient and public involvement

None.

RESULTS

A total of 890 study participants completed the study, with a response rate of 90%. The median age of the participants was 50 years (IQR 36–60), and only a third (276, 30.8%) were urban residents (table 1).

Clinical characteristics of the study participants

The median fasting blood glucose level was 148 mg/dL (IQR: 125–172.5 mg/dL). On the other hand, the median systolic and diastolic blood pressure was 120 mm Hg (IQR: 120–130 mm Hg) and 78 mm Hg (IQR: 70–80 mm Hg), respectively. The median BMI was 23 kg/m² (IQR: 20.6–26.0 kg/m²) (table 2).

Ocular and systemic comorbidities

The most common ocular comorbidity, affecting three-fourths (663, 74.1%) of the study participants, was cataract. By a percentage of 38.5%, hypertension was the second top clinical comorbidity observed in adult patients with diabetes in Northwest Ethiopia (table 3).

Magnitude of DMO

The prevalence of DMO among adult patients with diabetes in Northwest Ethiopia was confirmed to be 25.8% (CI 23.1% to 28.8%).

Factors associated with DMO

Variables that met the assumptions for the χ^2 test were entered individually into the bivariate logistic regression

Table 1 Sociodemographic characteristics of adult patients with diabetes attending comprehensive specialised hospitals in Northwest Ethiopia, 2023 (N=890)

Variables	Category	Frequency	%
Sex	Female	400	44.7
	Male	495	55.3
Age (years)	18–27	92	10.3
	28–37	132	14.7
	38–47	253	28.3
	48–57	242	27.0
	58–97	97	19.7
Residence	Urban	276	30.8
	Rural	619	69.2
Marital status	Never married	70	7.8
	Married	701	78.3
	Divorced	48	5.4
	Widowed	76	8.5
Educational status	No formal education	139	15.5
	Primary education	350	39.1
	Secondary education	278	31.1
	College and above	128	14.3
Occupational status	Government	156	17.4
	Private	389	43.5
	Housewife	168	18.8
	Retired	135	15.1
	Others*	47	5.2
Health insurance	Yes	542	60.6
	No	353	39.4
Average family monthly income (Ethiopian birr)	<2500	266	29.7
	2501–4000	238	26.6
	4001–6520	205	22.9
	>6521	186	20.8

*Others included student, farmer and unemployed.
n, sample size.

model. Predictors with a p value of less than 0.2 were then included in the multivariable logistic regression. In the multivariable logistic regression, factors such as peripheral neuropathy, hypertension, poor blood glucose control, BMI, diabetes duration of 10 years or more and poor adherence to diabetes medications were statistically significantly associated with DMO.

The odds of DMO occurrence among participants with peripheral neuropathy were three times higher compared with study participants who had no peripheral neuropathy (adjusted OR (AOR)=3.02, 95% CI 1.76 to 5.29). Likewise, having hypertension increased the odds of DMO occurrence by about twofold (AOR=1.98, 95% CI 1.24 to 3.17).

Regarding obesity, obese participants were fivefold more likely to develop DMO compared with those who

Table 2 Clinical characteristics of adult patients with diabetes attending comprehensive specialised hospitals in Northwest Ethiopia, 2023 (N=890)

Variable	Frequency	%
VI		
No	647	72.7
Mild	70	7.9
Moderate	144	16.2
Severe and worse	29	3.2
Type of DM		
Type 1	199	22.2
Type 2	696	77.8
Duration of DM (years)		
<10	648	72.4
>10	247	27.6
Family history of DM		
Yes	338	37.8
No	557	62.2
Fasting blood glucose level		
Poor control	607	67.8
Good control	288	32.2
BP (mm Hg)		
Diastolic		
<90	748	83.6
≥90	147	16.4
Systolic		
<140	757	84.6
≥140	138	15.4
Mode of treatment		
Insulin	225	25.1
Tablets	499	55.8
Both insulin and tablets	171	19.1
BMI		
Underweight	214	23.9
Normal	459	51.3
Overweight	129	14.4
Obesity	93	10.4
Eye check-up practice		
Good practice	533	59.6
Poor practice	362	40.4
Adherence to medication		
Good	561	62.7
Poor	334	37.3
Awareness towards DM		
Yes	359	40.1
No	536	59.9

BMI, body mass index; BP, blood pressure; DM, diabetes mellitus; n, sample size; VI, visual impairment.

Table 3 Ocular and systemic comorbidity status of the study participants attending comprehensive specialised hospitals in Northwest Ethiopia, 2023 (N=890)

Comorbidity	Frequency	%
Cataract		
Yes	663	74.1
No	232	25.9
Glaucoma		
Yes	147	16.4
No	748	83.6
Diabetic retinopathy		
Yes	140	15.6
No	755	84.4
Diabetic peripheral neuropathy		
Yes	145	16.2
No	750	83.8
Diabetic nephropathy		
Yes	241	26.9
No	654	73.1
Chronic foot ulcer		
Yes	161	18.0
No	734	82.0
Hypertension		
Yes	343	38.3
No	552	61.7
Chronic kidney disease		
Yes	139	15.5
No	756	84.5
n, sample size.		

were underweight (AOR=5.03, 95% CI 2.50 to 10.13). In contrast, preserving normal weight had a protective effect by reducing the odds of developing DMO occurrence by 99.5% compared with those who were underweight (AOR=0.05, 95% CI 0.03 to 0.10).

Suffering from DM for 10 years or above increased the odds of developing DMO by almost fourfold compared with those diagnosed with DM within the past 10 years (AOR=3.78, 95% CI 2.24 to 6.24). Moreover, DMO occurrence was two times more likely in patients with DM who adhered to their DM medications compared with those who did not adhere (AOR=2.06, 95% CI 1.32 to 3.22).

This study was able to identify that the odds of DMO occurrence were 5.06 times higher among the participants with poorly controlled blood glucose level than those with good blood glucose level (AOR=5.06, 95% CI 2.96 to 8.67).

Finally, this study unveiled that participants who had poor adherence to DM medications had above twofold higher odds of developing DMO compared with their comparators (AOR=2.06, 95% CI 1.32 to 3.22) (table 4).

DISCUSSION

DMO poses significant social, economic and psychological challenges to patients; however, the true extent of this burden has not been thoroughly investigated. Policy-makers may be motivated by baseline data on the genuine impact of DMO across different segments of the community, which could lead to informed, efficient changes in clinical practice that enhance quality of life. This multicentre study evaluated the burden of DMO among patients with diabetes and identified its predictors across a broad study area.

The prevalence of DMO in this study was 25.8% (95% CI 23.1 to 28.8). This finding is comparable to a study conducted in Debre Markos (26.3%)²⁴ and Italy (27.5%).³⁴ In contrast, the prevalence of DMO in this study is lower than in a previous study conducted in China (39.3%).³⁵ Variations in instruments used to detect DMO may be the reason for the decrease in prevalence. In the study from China, DMO was diagnosed using OCT, which is highly computerised and more sensitive in detecting macular oedema, compared with the slit lamp biomicroscope with Volk lens used in our study.^{5 15}

The prevalence of DMO was higher in this study compared with the prevalence reported from Gondar (17%),¹³ India (2.3%),³⁶ China (13.5%),³⁷ Turkey (15.3%),³⁸ Finland (9.5%)³⁹ and Poland (4.81%).⁴⁰ Variations in study set-up could be a possible reason for this discrepancy. Evidence from China was conducted on the community who was found in relatively healthy condition, whereas this study enrolled participants from hospitals seeking care for their illness. Therefore, this study had a higher chance of enrolling subjects at higher risk of developing DMO. Significant differences in sample size could be another cause of inconsistencies in prevalence, especially with evidence from Finland. In advance, sociodemographic differences were also other probable reasons. For instance, a study carried out in Poland showed that the prevalence of DMO was higher in type 1 DM than in type 2 DM. However, in our study, the magnitude of DMO was higher in patients with type 2 DM.⁴⁰

The odds of DMO occurrence among the study participants with peripheral neuropathy were three times higher as compared with non-peripheral neuropathy. This finding is consistent with studies done in Japan⁴¹ and Turkey.³⁸ The relationship between diabetic peripheral neuropathy and DMO is significant in individuals living with DM. This association could be highly determined by complications of neuropathy. Neuropathy has various complications of the retinal blood vessels like nerve fibre damage, which is linked to inflammatory processes, metabolic disturbances as well as elevated blood glucose levels within blood vessels. Those complications leads to ischemia, abnormal new blood vessels, and leakages of blood vessels having a facilitating role in DMO development.

Participants who had hypertension had twofold higher odds of developing DMO compared with study subjects without hypertension. This finding is in agreement with studies conducted in Debre Markos¹⁴ and Turkey.³⁸ The

Table 4 Factors associated with DMO among study subjects attending comprehensive specialised hospitals in Northwest Ethiopia, 2023 (N=890)

Variables	DMO		COR (95% CI)	AOR (95% CI)	P value
	Yes	No			
Peripheral neuropathy					
Yes	63	82	2.63 (1.82 to 3.82)	3.05 (1.76 to 5.29)	0.00
No	168	577	1.00	1.00	
Hypertension					
Yes	149	192	4.42 (3.21 to 6.07)	1.98 (1.24 to 3.17)	0.00
No	82	467	1.00	1.00	
Fasting blood glucose					
Poor	202	400	4.51 (2.96 to 6.86)	5.06 (2.95 to 8.67)	0.00
Good	29	259	1.00	1.00	
Nephropathy					
Yes	80	155	1.72 (1.24 to 2.38)	1.56 (0.98 to 2.51)	0.06
No	151	504	1.00	1.00	
BMI					
Underweight	74	135	1.00	1.00	
Normal	17	442	0.07 (0.04 to 0.12)	0.05 (0.03 to 0.10)	0.00
Overweight	67	62	1.97 (1.26 to 3.08)	1.53 (0.89 to 2.62)	0.12
Obesity	73	20	6.65 (3.76 to 11.77)	5.03 (2.5 to 10.13)	0.00
Duration of DM (years)					
<10	104	540	1.00	1.00	
≥10	127	119	5.54 (3.99 to 7.68)	3.78 (2.29 to 6.24)	0.00
Family history of DM					
Yes	109	226	1.71 (1.26 to 2.32)	1.03 (0.64 to 1.64)	0.89
No	122	433	1.00	1.00	
Eye check-up practices					
Good	122	406	1.00	1.00	
Poor	109	253	1.43 (1.06 to 1.94)	1.41 (0.84 to 2.07)	0.22
Adherence to DM medication					
Good	91	468	1.00	1.00	
Poor	141	191	3.77 (2.75 to 5.15)	2.06 (1.32 to 3.22)	0.00

AOR, adjusted OR; BMI, body mass index; COR, Crude odd ratio; DM, diabetes mellitus; DMO, diabetic macular oedema.

possible attributable reason for this occurrence might be elevated blood pressure. Hypertension and DMO are associated with increased blood pressure in the blood vessels. Elevated blood pressure within the arteries leads to the breakdown of the internal blood–retinal barrier, resulting in the accumulation of fluid in the macular area. In addition, long-term hypertension can result in hypertensive retinopathy, which can cause several problems such as haemorrhage, fluid leakage in the retina and blood vessel narrowing due to persistently high blood pressure, aggravating the development of macular oedema.⁴²

For participants who were obese, the odds of DMO occurrence were five times higher compared with underweight participants. This finding is in line with studies done in the USA⁴³ and Finland.⁴⁴ Obesity is highly linked

to chronic low-grade inflammation, oxidative stress and dysregulation of adipokines and cytokines, which can be considered contributing factors to blood–retinal barrier breakdown and DMO development. This condition could be facilitated by comorbidities such as hypertension and dyslipidaemia, which can aggravate the development of DMO.⁴⁵ Furthermore, obesity has also been linked to metabolic dysregulation and chronic complications.

On the contrary, preserving normal weight decreases the odds of developing DMO occurrence by 95% compared with those who were underweight. This condition might occur because preserving normal weight for height minimises the occurrence of complications and related inflammation, which has a role in DMO development. In the development of DMO, normal weight can

have a protective effect. Having normal weight is not only advantageous by reducing the occurrence of DMO, but it also has an unprecedented role in achieving good prognostic outcomes of visual functioning following DMO treatment.⁴⁶ Therefore, it is better to underscore weight management strategies in patients with diabetes to prevent the development of DMO and its vision-threatening consequences.

The odds of DMO occurrence were four times higher among participants who had a duration of DM of 10 years or more compared with a duration of less than 10 years. This is in line with the studies done in Debre Markos and Gondar in Ethiopia,^{13 14} as well as in India,¹⁹ Turkey³⁸ and China.³⁷ As the duration of DM gets longer, the patient becomes more prone to developing complications. As time goes by, the progressive damage to retinal microvasculature and the associated inflammatory processes goes to be experienced that could enable DMO. This finding shows that understanding the relationship between the duration of DM and DMO is crucial for early detection, close monitoring and timely intervention to prevent vision loss due to DMO.

Inappropriate use of DM medications increases the odds of DMO occurrence twofold. Complications that occurred due to poor adherence to medications could be the reason behind this. Medication non-adherence in patients with diabetes can lead to substantial complications and worsening of the disease progression of DM, facilitating the development of DMO. Therefore, addressing poor adherence to diabetes medications is crucial to preventing vision loss due to DMO, which can be done by emphasising patient education and providing support and comprehensive care to patients with diabetes.

Regarding glycerol control, the odds of DMO occurrence were five times higher among the study participants who had poor glycerol control as compared with those with good glycerol control. This finding is consistent with the studies conducted in Gondar and Debre Markos in Ethiopia,^{13 14} as well as in the USA^{47 48} and China.⁴⁹ The probable reason for this association might be the hyperglycaemic effect. As the blood glucose level increases in the retinal blood vessel, hypoxia is induced. To overcome this hypoxia, the retina's blood vessels begin to produce aberrant blood vessels and increase blood flow towards hypoxia. This facilitates the development of DMO.¹⁴

Strengths and limitations of this study

The novelty of this study was its better representativeness of the general population and its provision of up-to-date information. This was achieved through a multicentre study design that incorporated a diverse population across various resource-constrained settings and regions. Additionally, the inclusion of a sufficient sample size enhanced the study's statistical power, thereby increasing its reliability.

This study had some limitations, primarily due to its reliance on self-reported interviews, which may introduce biases such as social desirability and recall bias. To address

these concerns, we allocated sufficient time during pretesting for accurate recall and ensured participants understood data safety measures through clear instructions and monitoring. Second, the restricted availability of lipid profiles (total cholesterol, HDL-C, LDL-C) and creatinine levels, as well as haemoglobin A1c (HbA1c) tests to assess blood glucose, hindered our ability to fully explore the associations between these factors. Due to resource limitations in HbA1c testing, we opted to use fasting glucose measurements as an alternative. Additionally, the lack of access to advanced diagnostic tools such as optical coherence tomography (OCT) further constrained our capabilities. Patients with conditions such as mature cataracts or dense media opacities were excluded from the study due to their impact on posterior fundus visualisation. This exclusion may result in an underestimation of the true magnitude of DMO.

Despite these limitations, the findings of this study provide valuable insights that can enhance clinical services and inform future research initiatives, particularly in developing countries and among economically disadvantaged or underserved populations.

We recommend that future researchers conduct longitudinal studies to elucidate the natural progression of DMO over time using advanced instruments such as OCT. It would also be beneficial to include lipid profiles and HbA1c levels to examine the association of these factors. Additionally, we suggest addressing interobserver variability to reduce discrepancies in diagnostic criteria and interpretation of DMO.

CONCLUSION

This study showed that a quarter of patients with diabetes in Northwest Ethiopia had clinically significant DMO. Peripheral neuropathy, obesity, long duration of DM, hypertension, poor glycerol control and poor adherence to DM medications were factors significantly associated with DMO. Controlling diabetic complications, comorbidities and stability of biomarkers through evidence-based, integrated and patient-centred interventions that ultimately focus on medication adherence and physical exercise is vital. Furthermore, as the duration of DM increases, frequent screening and monitoring of the fundus is recommended for early detection and treatment of DMO.

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Patient consent for publication Obtained.

Ethics approval This study involves human participants. Ethical clearance was obtained from the University of Gondar College of Medicine and Health Science, School of Medicine Ethical Review Committee (approval number 622/2023). Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available upon reasonable request. All data relevant to the study are included in the article or uploaded as supplementary information.

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