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Symptomatic dry eye disease and its associated factors among adult patients with diabetes attending comprehensive specialised hospitals in Amhara Region, Ethiopia: a multicentre institution-based cross-sectional study

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ABSTRACT

Objective This study aimed to determine the prevalence and associated factors of symptomatic dry eye disease (SDED) among adult patients with diabetes visiting five comprehensive specialised hospitals in the Amhara Region, Ethiopia.

Design An institution-based cross-sectional study.

Setting This study was conducted at the University of Gondar, Debretabor, Tibebe Gion, Felege Hiwot and Debre Markos comprehensive specialised hospitals in the Amhara Region, Ethiopia, from 8 May 2023 to 8 June 2023.

Participants The study included 1199 adult patients with diabetes aged >18 years who lived in the Amhara Region, Ethiopia, for more than 6 months and were selected using a systematic random sampling technique.

Primary and secondary outcome measures In this study, the primary outcome measure was the magnitude of SDED, and the secondary outcome measure was the associated factors of SDED.

Results A total of 1134 study subjects participated in this study with a response rate of 94.5%. The prevalence of symptomatic dry eye was 40.4% (95% CI 37.7 to 43.2). Factors such as poor glycaemic control (adjusted OR (AOR)=2.58, 95% CI 1.86 to 3.58), duration of diabetes ≥10 years (AOR=2.77, 95% CI 1.95 to 3.95), proliferative diabetic retinopathy (AOR=5.58, 95% CI 2.1 to 14.39), poor eye check-up practice (AOR=1.98, 95% CI 1.49 to 2.62) and peripheral diabetic neuropathy (AOR=3.76, 95% CI 2.58 to 5.48) were significant associated factors with SDED.

Conclusion In this study, the prevalence of SDED among patients with diabetes was high. Poor glycaemic control, longer duration of diabetes, proliferative diabetic retinopathy, inadequate eye check-up practices and peripheral diabetic neuropathy were significantly associated with SDED. It is recommended that healthcare providers prioritise regular monitoring of eye health in patients with diabetes, emphasising the importance of maintaining optimal glycaemic control, and routine eye check-ups for early detection and management of SDED.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study employed a multicentre design, which increases the generalisability of the findings across different specialised hospitals.
⇒ The use of standardised diagnostic criteria for symptomatic dry eye disease minimised measurement bias.
⇒ A large sample size was included, enhancing the statistical power of the study.
⇒ The cross-sectional design limits the ability to establish causal relationships between dry eye disease and associated factors.
⇒ Potential recall bias may have influenced the accuracy of self-reported data on symptoms and medical history.

INTRODUCTION

Diabetes mellitus is a significant global public health issue, leading to various eye complications such as diabetic retinopathy, cataracts, glaucoma, keratopathy and dry eye disease.[1 2]

Symptomatic dry eye disease (SDED) is a severe form of dry eye disease commonly found in the diabetic population.[3] According to the international workshop, dry eye disease is defined as a complex condition of the eye surface characterised by an imbalance in the tear film, accompanied by eye symptoms. This imbalance includes tear film instability[4] and hyperosmolarity, as well as ocular surface inflammation and damage, and neurosensory abnormalities.[5]

Table 1 Sociodemographic characteristics of adult patients with diabetes visiting comprehensive specialised hospitals in the Amhara Region, Ethiopia 2023 (n=1134)

Variables	Categories	Symptomatic dry eye disease	
		Yes	No
Age (in years)	18–27	44 (9.6%)	74 (10.9%)
	28–37	68 (14.8%)	101 (14.9%)
	38–47	76 (16.5%)	94 (13.9%)
	48–57	122 (26.6%)	169 (25.0%)
	>57	148 (32.3%)	238 (35.2%)
Sex	Male	249 (54.3%)	370 (54.7%)
	Female	209 (45.6%)	306 (45.2%)
Residency	Urban	329 (71.8%)	471 (69.6%)
	Rural	129 (28.1%)	205 (30.3%)
Educational status	No formal education	89 (19.3%)	135 (19.9%)
	Primary	150 (32.7%)	241 (35.6%)
	Secondary	120 (26.2%)	209 (30.9%)
	College and above	99 (21.6%)	91 (13.4%)
Occupational status	Government	75 (16.3%)	112 (16.5%)
	Private	181 (39.5%)	276 (40.8%)
	Housewife	94 (20.5%)	121 (17.8%)
	Retired	70 (15.2%)	104 (15.3%)
	Others*	38 (8.2%)	63 (9.3%)
Marital status	Single	35 (7.6%)	64 (9.4%)
	Married	360 (78.6%)	519 (76.7%)
	Divorced	29 (6.3%)	44 (6.5%)
	Widowed	34 (7.4%)	49 (7.2%)
Health insurance	Yes	285 (62.2%)	421 (62.2%)
	No	173 (37.7%)	255 (37.7%)
Average family monthly income (in Ethiopian Birr)	≤2500	124 (27.0%)	174 (25.7%)
	2501–4000	106 (23.1%)	169 (25.0%)
	4001–6500	102 (22.2%)	176 (26.0%)
	≥6501	126 (27.5%)	157 (23.2%)

Average family monthly income was classified using interquartile.
*Other: Includes student, no job and farmer.

Dry eye disease is characterised by ocular discomfort, burning sensation, blurring of vision, eye fatigue, grittiness, photophobia, soreness, irritation and tearing.[4] These symptoms have significant impacts on individuals and healthcare services, including a reduction in vision-related quality of life, compromised performance of daily activities and loss of productivity.[6]

The prevalence of SDED has rapidly increased due to the growing diabetic population worldwide.[7] Globally, the prevalence of SDED ranges from 12.3% to 62.4% in the adult population.[4] In Ethiopia, studies have shown that the prevalence of SDED ranges from 43% to 50.5% among the general population, while among patients with diabetes, the prevalence is 34.8%.[7]

Research has shown that older age, female sex, poor glycaemic control, long duration of diabetes, peripheral diabetic neuropathy, use of artificial tears, diabetic retinopathy, proliferative diabetic retinopathy and a history of cataract surgery were positively associated with dry eye disease.[2 7 8] SDED represents a significant public health concern due to its adverse effects on vision and quality of life. Moreover, a substantial proportion of patients with diabetes have reported experiencing at least one symptom of dry eye disease.[6]

Research indicates that the prevalence of SDED among patients with diabetes is influenced by both geographical and racial factors. A study analysing a large patient population in North Carolina found that Asian individuals with diabetes had a higher likelihood of developing SDED compared with other racial groups, suggesting a significant racial disparity in SDED prevalence among diabetics.[9] Additionally, a systematic review identified East Asian ethnicity as a consistent non-modifiable risk factor for SDED, highlighting the importance of considering racial background in assessing SDED risk.[10] However, another study focusing on US men reported no significant variations in SDED prevalence among different racial or ethnic groups, indicating that the impact of racial factors may vary depending on the population studied.[11]

These findings underscore the need for further research to elucidate the complex interplay between geographical

Table 2 Clinical, ocular and systemic characteristics of adult patients with diabetes visiting comprehensive specialised hospitals in Amhara Region, Ethiopia 2023 (n=1134)

Variable	Symptomatic dry eye disease	
	Yes	No
Type of diabetes		
Type 1	869 (18.7%)	180 (26.6%)
Type 2	372 (81.2%)	496 (73.3%)
Glycaemic control		
Poor control	388 (84.7%)	447 (66.1%)
Good control	70 (15.2%)	229 (33.4%)
Duration of DM (in years)		
<10	315 (68.7%)	603 (89.2%)
≥10	143 (31.2%)	73 (10.7%)
Family history of diabetes		
Yes	163 (35.5%)	244 (36.0%)
No	295 (64.4%)	432 (63.9%)
Mode of diabetes treatment		
Insulin	117 (25.5%)	195 (28.8%)
Tablets	281 (61.3%)	370 (54.7%)
Both insulin and tablets	60 (13.1%)	111 (16.4%)
Adherence to diabetes medication		
Good	244 (53.2%)	405 (59.9%)
Poor	214 (46.7%)	271 (40.0%)
Peripheral diabetic neuropathy		
No	343 (74.8%)	619 (91.5%)
Yes	111 (24.2%)	57 (8.4%)
Diabetic nephropathy		
No	385 (84.0%)	555 (82.1%)
Yes	73 (15.9%)	121 (17.8%)
Chronic foot ulcer		
No	394 (86.0%)	580 (85.7%)
Yes	64 (13.9%)	96 (14.2%)
Hypertension		
No	306 (66.8%)	480 (71.0%)
Yes	152 (33.1%)	196 (28.9%)
BMI (kg/m^2)		
Underweight	75 (16.3%)	90 (13.3%)
Normal	219 (47.8%)	322 (47.6%)
Overweight	107 (23.3%)	160 (23.6%)
Obesity	57 (12.4%)	104 (23.6)
Proliferative diabetic retinopathy		
Yes	29 (6.3%)	6 (1.3%)
No	429 (93.6%)	670 (99.1%)
Glaucoma		
Yes	87 (18.9%)	79 (11.6%)
No	371 (54.8%)	597 (88.3%)
Eye check-up practices		
Good practice	207 (45.1%)	456 (67.4%)
Poor practice	251 (54.8%)	220 (32%)
Category of visual impairment		
Normal	283 (61.7%)	454 (67.1%)
Mild	43 (9.3%)	53 (7.8%)
Moderate	115 (25.1%)	153 (22.6%)
Severe	13 (2.8%)	12 (1.7%)
Blindness	4 (0.8%)	4 (0.5%)

BMI, body mass index; DM, diabetes mellitus.

location, racial background and the prevalence of SDED among patients with diabetes.

Despite the growing significance of SDED, there is a lack of empirical evidence regarding its magnitude and associated factors, particularly within the study area. Therefore, the aim of this study was to assess the prevalence and identify the factors associated with SDED among adult patients with diabetes attending five comprehensive specialised hospitals in the Amhara Region, Ethiopia.

METHODS AND MATERIALS

Study design, setting and period

A multicentre cross-sectional study was conducted at five hospitals within the Amhara Region of Ethiopia, namely, the University of Gondar, Debre Tabor, Tibebe Gion, Felege Hiwot and Debre Markos Hospitals. The study was carried out at the diabetic care clinics of these hospitals from 8 May 2023 to 8 June 2023. In the Amhara Region, there are eight comprehensive specialised hospitals, including the University of Gondar, Felege Hiwot, Tibebe Gion, Debre Tabor, Debre Markos, Debre Birhan, Dessie and Woldia Hospitals. By using a random sampling technique, the study area was selected from those hospitals. Each of the selected hospitals provides specialised care for both diabetic and eye care services.

Study population and eligibility criteria

All adult patients aged 18 years and older, diagnosed with either type 1 or type 2 DM by a healthcare professional and receiving diabetic care in the Amhara Region during the data collection period, were eligible to participate in the study. However, individuals with a history of eye surgery within the past month, those experiencing active ocular infections, recent ocular trauma or those who are critically ill were excluded from participation.

Table 3 Factors associated with SDED among patients with diabetes visiting comprehensive specialised hospitals in the Amhara Region, Ethiopia 2023 (n=1134)

Variables	Symptomatic dry eye disease				
	Yes	No	COR (95%confidence interval)	AOR (95%confidence interval)	P value
Educational status					
Not formal education	89	135	1.00	1.00	
Primary	150	241	0.94 (0.67–1.32)	0.70 (0.48–1.02)	0.068
Secondary	120	209	0.87 (0.61–1.23)	0.75 (0.51–1.11)	0.61
College and above	99	91	1.65 (1.11–2.13)	1.4 (0.91–2.14)	0.123
Type of diabetes					
Type I	86	180	1.00	1.00	
Type II	372	496	1.56 (1.17–2.09)	1.22 (0.87–1.70)	0.234
Glycaemic control					
Good	70	229	1.00	1.00	
Poor	388	447	2.83 (2.10–3.83)	2.58 (1.86–3.58)	0.001
Duration of diabetes(in year)					
<10	315	603	1.00	1.00	
≥10	143	73	3.74 (2.74–5.12)	2.77 (1.95–3.95)	<0.0001
Diabetic medication adherence					
Good	244	405	1.00	1.00	
Poor	214	271	1.31 (1.03–1.66)	1.12 (0.86–1.47)	0.381
Peripheral diabetic neuropathy					
Yes	111	57	3.47 (2.45–4.90)	3.76 (2.58–5.48)	<0.0001
No	347	619	1.00	1.00	
Hypertension					
Yes	152	196	1.21 (0.94–1.57)	0.92 (0.68–1.24)	0.619
No	306	480	1.00	1.00	
Proliferative diabetic retinopathy					
No	429	670	1.00	1.00	
Yes	29	6	7.54 (3.10–18.33)	5.58 (2.16–14.39)	<0.0001
Glaucoma					
Yes	87	79	1.77 (1.27–2.46)	1.17 (0.79–1.72)	0.416
No	371	597	1.00	1.00	
Eye check-up practice					
Yes	251	220	2.51 (1.96–3.20)	1.98 (1.49–2.62)	<0.0001

Continued

Table 3 Continued

Variables		Symptomatic dry eye disease				
		Yes	No	COR (95% confidence interval)	AOR (95% confidence interval)	P value
No		207	456	1.00	1.00	

AOR, adjusted OR; COR, crude odd ratio; SDED, symptomatic dry eye disease.

Sample size determination and sampling procedure

To determine the sample size, the single population proportion formula $n = \frac{(Z_{\alpha/2})2 * P(1-P)}{d^2}/d^2$ was used. In this formula, n represents the sample size, Z represents the value of the z statistic at a 95% confidence level (which is 1.96), P represents the expected proportion of SDED (34.8% based on a similar study in Hawassa, Ethiopia[7]) and d represents the margin of error (4%). The calculated sample size was 545. By considering the design effect of 2 to overcome the uncovered area in the study setting and a 10% non-response rate, the final sample size was determined to be 1199.

Five hospitals were selected using a simple random sampling technique from eight comprehensive specialised hospitals in the Amhara Region of Ethiopia. Study participants were recruited from these five hospitals, which serve approximately 2660 patients with diabetes each month. Proportional allocation was applied to each hospital, resulting in the following distribution of participants: University of Gondar: 327; Debre Tabor: 72; Felege Hiwot: 406; Tibebe Gion: 79; and Debre Markos: 315. Participants were then selected using a systematic random sampling method, which involved calculating a sampling interval of 2. The lottery method was used to randomly select the first two participants, and subsequently, every other participant was included in the study.

Operational definitions

Symptomatic dry eye: Was defined as those participants who had a score of 13 points and above based on the Ocular Surface Disease Index (OSDI) questionnaire score.[7]

Glycaemic control: Was categorised as good if the recorded current fasting blood sugar (FBS) level was <130 mg/dL and poor if the current FBS level was 130 mg/dL and above.[12]

Eye check-up practices: Participants who underwent an ophthalmic examination within the past 1 year are considered to have good eye check-up practices, while those who have not had an ophthalmic examination within the past 1 year are considered to have poor eye check-up practices.[13]

Medication adherence: Participants who scored below the median value of 6 in self-reported adherence to diabetic medication questions were considered to have poor adherence, while those scoring 6 or above were classified as having good adherence.[14]

Body mass index (BMI) (kg/m^2): Was categorised based on the WHO categorisation and calculated as weight in kilograms divided by height in square metres (m^2). A BMI of <18.5 kg/m^2 was considered underweight, a BMI of 18.5–24.9 kg/m^2 was considered normal, a BMI of 25–29.9 kg/m^2 was considered overweight, and a BMI of ≥30 kg/m^2 was considered obese.[7]

Proliferative diabetic retinopathy: Define 'Yes' if the patients have a known history of proliferative retinopathy or if any of the following are present: neovascularisation

Table 4 A literature review on the prevalence and key factors of SDED in patients with diabetes across different regions

Author name	Country	Year of publication	Study population	Study design	Key findings
Current study Shumye *et al*	Gondar, Ethiopia	2025	Patients with diabetes	Cross-sectional	Found a prevalence of 40.4%. Poor glycaemic control, longer duration of diabetes, diabetic retinopathy, peripheral neuropathy and eye check-up practices were significant factors.
Bekele *et al*[7]	Hawassa, Ethiopia	2023	Patients with diabetes	Cross-sectional	Prevalence of 34.8%. Poor glycaemic control and longer duration of diabetes were strongly associated with SDED.
Nadeem *et al*[8]	Pakistan	2019	Patients with type 2 diabetes	Cross-sectional	Found high prevalence of 76.5%. Peripheral neuropathy and poor glycaemic control were major contributing factors.
Shaikh *et al*[31]	India	2020	Patients with diabetes	Cohort study	Prevalence of 36%. Effective glycaemic control reduces SDED risk, and longer duration of diabetes increases it.
Jie *et al*[33]	China	2019	Patients with diabetes	Case-control study	Prevalence of 21%. Glycaemic control and peripheral neuropathy were linked to higher rates of SDED.
Ogundo *et al*[25]	Kenya	2018	Patients with diabetes	Cross-sectional	Prevalence of 49.8%. Diabetic retinopathy and peripheral neuropathy were associated with high SDED rates.
Ribeiro *et al*[32]	**Maceio, Brazil**	**2017**	General population	Cross-sectional	Prevalence of 26.2%. Diagnosed based on OSDI scoring, excluding mild cases.
Alshamrani *et al*[29]	**Saudi Arabia**	**2020**	Patients with diabetes	Cross-sectional	Prevalence of 32.1%. Poor eye check-up practices were linked to a higher prevalence of undiagnosed SDED.
Graue-Hernández *et al*[6]	**Mexico**	**2017**	Patients with diabetes	Cross-sectional	Prevalence of 41.1%. Duration of diabetes and poor glycaemic control were significant factors.
Manaviat *et al*[26]	**Yazd, Iran**	**2015**	Patients with diabetes	Cross-sectional	Prevalence of 54.3%. Duration of diabetes and poor glycaemic control were associated with higher SDED rates.

Continued

Table 4 Continued

Author name	Country	Year of publication	Study population	Study design	Key findings
Bashorun *et al*[27]	Nigeria	2018	Patients with diabetes	Cross-sectional	Prevalence of 63.95%. Diabetic retinopathy and peripheral neuropathy were key contributors to SDED.
Cai *et al*[46]	East Asia	2022	Patients with diabetes	Systematic review	Found a prevalence of approximately 27.76%. East Asian ethnicity was identified as a non-modifiable risk factor.

SDED, symptomatic dry eye disease.

of the retina or optic nerve head, preretinal or vitreous haemorrhage, and tractional retinal detachment.[15]

Glaucoma: Was defined as an intraocular pressure greater than 21 mm Hg or an asymmetry of more than 4 mm Hg between the two eyes, along with the presence of optic nerve damage, indicated by a vertical cup-to-disc (C/D) ratio of ≥0.5, a C/D asymmetry of ≥0.1 between the two eyes, or characteristic visual field defects associated with optic disc damage or elevated IOP. Additionally, *low-tension glaucoma* was defined as the presence of optic nerve damage and characteristic visual field defects despite an IOP ≤21 mm Hg, after excluding other possible causes of optic neuropathy.[16–18]

Peripheral neuropathy: Define 'Yes' if the patients have a known history of peripheral neuropathy or often present with varying degrees of numbness, tingling, aching, burning sensation, weakness of limbs, hyperalgesia, allodynia and pain. This pain has been characterised as superficial, deep-seated or severe, unremitting pain with exacerbation at night.[19]

Diabetic nephropathy: Define 'Yes' if the patients have a known history of diabetic nephropathy or have been classically defined by the presence of proteinuria >0.5 g/24 hours.[20]

Hypertension was defined as 'yes' if the systolic and diastolic blood pressure were greater than or equal to 140/90 mm Hg or if there is known history of hypertension.[21]

Data collection procedures

Data for the study were collected using an Amharic version of a pretested, semistructured questionnaire that included sections on clinical variables, SDED and sociodemographic characteristics. Five trained ophthalmic nurses and five optometrists conducted face-to-face interviews to collect SDED data and reviewed medical records for clinical information.

The OSDI questionnaire included questionnaire, demographic information, clinical data and information on ocular and systemic comorbidities (online supplemental file 1). Data on systemic comorbidities and clinical data such as peripheral neuropathy, diabetic nephropathy, chronic foot ulcer, type of diabetes, treatment method, duration of diabetes, and current fasting blood sugar level and hypertension were collected through a comprehensive review of the patient's medical records and patient-reported history to ensure the inclusion of both documented clinical assessments and self-reported health information for accuracy and completeness. Additionally, data were collected on the presence of glaucoma as a potential factor, given that both the condition and its treatment may affect the tear film and ocular surface.

SDED was evaluated using the OSDI questionnaire, which consists of 12 questions. Each question was scored from 0 to 4, where 0 represents 'none of the time,' 1 represents 'some of the time,' 2 represents 'half of the time,' 3 represents 'most of the time' and 4 represents 'all of the time'. The reliability of the

items was assessed by calculating Cronbach's alpha value, which was found to be 0.94.

After completing a personal interview, each study participant underwent a comprehensive eye examination. The presenting visual acuity of participants was measured in each eye using a Snellen acuity chart at a distance of 3 m, taking into account the limitations of the study setting, including available space and patient comfort. An examination of the anterior and posterior segments of the eye was performed using a slit-lamp biomicroscope with a 90-diopter Volk lens. Pupil dilation was achieved with 1% tropicamide eye drops to facilitate the assessment of glaucoma and any signs of retinopathy.

Data quality control

The English version of the questionnaire was translated into Amharic by language experts and then back-translated into English to ensure consistency. A pretest was conducted on 5% (60) of the sample size at Debark General Hospital, and necessary modifications were made based on the results before the actual data collection began. Before data collection, the data collectors received half a day of training on interview procedures. During data collection, daily supervision and discussions were conducted to ensure accuracy. After data collection, the principal investigator reviewed all the collected data for completeness, accuracy and clarity. The data were then cleaned and cross-checked thoroughly before analysis.

Data processing and analysis

Data were entered into Kobo Collect V.2022.4.4 and subsequently exported to Stata V.14 for analysis. Descriptive statistics, including proportions, frequencies, ratios, and summary statistics, were calculated. A binary logistic regression was conducted to identify factors associated with SDED, with the strength of the association determined by the adjusted OR and a 95% CI. The goodness of fit of the model was assessed using the Hosmer-Lemeshow test. A p value <0.05 was considered statistically significant.

RESULTS

Sociodemographic characteristics of the study participants

A total of 1134 study participants participated in this study with a response rate of 94.5%. The median age of the participants was 53 years, with an IQR of 37–62 years. Out of 1134 participants, 619 (54.59%) were male and 800 (70.55%) were urban residents (table 1).

Diabetes-related complications among study participants

The median current fasting blood sugar was 152 mg/dL (IQR 128–180 mg/dL). In the study, the most systemic comorbidity was diabetic neuropathy (29.45%), followed by diabetic nephropathy (17.11%) and chronic foot ulcer (14.11%). Out of 1134 study participants, 35 (3.09%) had proliferative diabetic retinopathy (table 2).

Visual impairment status of study participants

Of the total number of patients with diabetes, 34.3% of study participants were visually impaired and 0.71% were blind considering the vision of the better eye (table 2).

Magnitude of SDED

This study found that the prevalence of SDED was 40.4% (95% CI 37.7% to 43.2%), of which 81.2% and 18.7% were found in type 2 and type 1 DM, respectively.

Factors associated with SDED

On bivariate logistic regression, educational status, presence of glaucoma, proliferative diabetic retinopathy, peripheral neuropathy, hypertension, type 2 diabetes, duration of diabetes, poor glycaemic control, poor eye check-up practice and poor diabetes medication adherence were significantly associated factors. After multivariable binary logistic regression analysis was done, proliferative diabetic retinopathy, peripheral neuropathy, duration of diabetes, poor glycaemic control and poor eye check-up practice were independently and significantly associated with SDED.

Participants who had poor glycaemic control were 2.58 times (adjusted OR (AOR)=2.58, 95% CI 1.86 to 3.58) more likely to have SDED as compared with participants with good glycaemic control. Participants with a duration of diabetes 10 years and above were 2.77 times (AOR=2.77, 95% CI 1.95 to 3.95) more likely to develop SDED than participants with a duration of diabetes of less than 10 years.

The odds of SDED was 5.58 times higher among participants with proliferative diabetic retinopathy than participants with non-proliferative diabetic retinopathy (AOR=5.58, 95% CI 2.1 to 14.39).

The odds of having SDED was 1.98 times higher in participants with poor eye check-up practice than in participants who had good eye check-up practice (AOR=1.98, 95% CI 1.49 to 2.62). Moreover, participants with peripheral diabetic neuropathy were 3.76 times more likely to have SDED than participants without peripheral diabetic neuropathy (AOR=3.76, 95% CI 2.58 to 5.48) (table 3).

DISCUSSION

SDED is one of the most common eye disorders among individuals with DM[1] and can significantly impact their quality of life. The prevalence of this condition varies considerably across different geographical regions, climates and lifestyle factors, with reported rates ranging from 5% to 35%.[22]

A recent systematic review indicates that Africa has the highest prevalence of SDED, with studies reporting rates as high as 47.52%. In comparison, Asia has a significant prevalence of approximately 27.76%. Other regions, such

as Europe and the Middle East, estimated moderate rates, while North America has the lowest prevalence of SDED of approximately 5.5%.[23] A study conducted in Africa is essential for addressing modifiable factors related to SDED.

This particular research focused on the prevalence of SDED among patients with diabetes in the Amhara Region, revealing that the prevalence of SDED was 40.4% among this population. This finding was in line with a study conducted in Mexico (41.1%).[6]

However, the prevalence observed in this study is lower than that reported in studies conducted in India (43.8%),[24] Pakistan (76.5%),[8] Kenya (49.8%),[25] Yazd (54.3%)[26] and Nigeria (63.95%).[27] The possible reason for this discrepancy may be attributed to variations in study populations and design. For instance, the study in Pakistan exclusively included patients with type 2 diabetes, who are at a higher risk of developing dry eye disease, whereas our study encompassed both patients with type 1 and type 2 diabetes, which may have contributed to a lower observed prevalence. Furthermore, the Saudi Arabian study included both paediatric and adult populations, while our study focused solely on adults, potentially leading to a higher prevalence in the Saudi study due to the inclusion of paediatric cases. Additionally, geographical and environmental factors, such as climate and lifestyle, may influence the prevalence rates,[10 28] providing further context for the observed differences across studies.

The result of this study was higher than that of previous studies conducted in Hawassa, Ethiopia (34.8%),[7] Saudi Arabia (32.1%),[29] the USA (14.4%),[30] India (36%),[31] Maceió, Brazil (26.2%)[32] and China (21%).[33] The observed variation may be attributed to the differences in sociodemographic factors, sample sizes, diagnostic criteria, study populations and geographical variation. For example, studies conducted in developed countries such as the USA, Saudi Arabia and China reported a lower prevalence of SDED, likely due to more effective eye screenings and better control of blood sugar levels. Additionally, a small sample size may lead to an underestimation of the prevalence of SDED. For instance, a study in India with only 100 participants[34] may not have accurately reflected the true prevalence. In contrast, our study used a sufficient sample size and was conducted across multiple centres, which enhances the reliability of the findings and is more likely to accurately capture the magnitude of SDED. Furthermore, in a study conducted in Maceió, Brazil, dry eye disease was diagnosed as moderate to severe based only on the OSDI scoring category, excluding mild cases, whereas our study included mild cases as well.[32] This difference in the criteria used for diagnosis may explain the lower prevalence of dry eye in Maceió. Differences in study populations were also another factor contributing to the discrepancies observed in research findings. For example, a study conducted in China examined SDED among the general population, while the current study focuses on a high-risk group, specifically patients with diabetes. This variation in the populations being studied likely exacerbates the differences observed in the results of this investigation. Furthermore, geographical variation had an additional reason for this variation magnitude. A study done in Europe, Asia and the USA showed lower magnitude of SDED as compared with African countries due to differences in living standards.

Participants who had poor glycaemic control were 2.58 times (AOR=2.58, 95% CI 1.86 to 3.58) more likely to have SDED as compared with participants with good glycaemic control. This result was in line with the studies conducted in Hawassa, Ethiopia,[7] Pakistan,[8] Shanghai and Assam, India[35] and China.[2] This positive association may be attributed to metabolic changes. Poor glycaemic control results in elevated glucose levels within the tear film, leading to increased viscosity (hyperosmolarity). A reduction in water content in the tear film affects the wettability of the cornea, thereby facilitating the onset of dry eye disease.[7 24] Research has shown that poor glycaemic control can disrupt both the stability and the production of the tear film. Specifically, elevated Hemoglobin A1C levels have been correlated with significantly lower Schirmer test scores, indicating reduced tear production and a worsening of dry eye symptoms.[36] This relationship underscores the impact of chronic hyperglycaemia on ocular health and tear dynamics.[37] Therefore, it is advisable to maintain better control of blood glucose levels to reduce the incidence of dry eye disease.

Participants with duration of diabetes of 10 years and above were 2.77 times more likely to develop SDED than participants with a duration of diabetes of <10 years. This result was in line with study conducted in Hawassa City, Southern Ethiopia,[7] Assam, India,[35] Western India[24] and Pakistan.[8] The positive association observed may be due to an increase in duration, which can compromise corneal sensation and lead to higher osmolality in the tear film. A longer duration of DM can result in several complications, including reduced corneal sensation and a lower blinking rate, which can lead to decreased lubrication of the cornea and increased evaporation of the tear film. Additionally, tear film hyperosmolarity can reduce tear production, further contributing to the development of dry eye disease.[3] Therefore, as the duration of DM increases, frequent ocular examination is necessary for early detection and management of the SDED.[24]

Participants with peripheral diabetic neuropathy were 3.76 times more likely to have SDED than participants without peripheral diabetic neuropathy. This finding was consistent with the study done in Pakistan,[8] New South Wales, Australia[38] and China.[39] This association may be due to a problem with innervation. If there is any issue with the innervation of corneal

sensation, the amount of tear production significantly reduces because peripheral neurons innervate the cornea and tear film production. Research shows that diabetic peripheral neuropathy can damage the corneal nerves, which are essential for maintaining both tear production and overall ocular surface health. A study found that patients with diabetic neuropathy had shorter corneal nerve fibres, and this reduction was independently linked to more severe dry eye symptoms. This suggests that loss of corneal innervation can impair tear secretion and contribute to the development of dry eye disease.[40–42]

The odds of SDED was 5.58 times higher among participants with proliferative diabetic retinopathy than participants without non-proliferative diabetic retinopathy. This finding was agreed with the study done in Pakistan.[8] The severity of diabetic retinopathy is positively correlated with the presence and severity of dry eye. Increased ocular surface inflammation and altered corneal innervation and sensitivity lead to the impairment of the lacrimal gland and ocular surface, resulting in reduced tear production and tear film instability associated with PDR. This facilitates the development of dry eye disease.[24]

The odds of having SDED was 1.98 times higher in participants with poor eye check-up practice than participants who had good eye check-up practice. This study was in agreement with a study done in Ethiopia[13] and Saudi Arabia.[43] This association could be due to poor eye check-up practices, leading to a high rate of undiagnosed dry eye disease. Poor eye check-up practices can be a risk factor for dry eye disease because of the lack of proper examination and evaluation of the ocular surface, tear film and related structures. A comprehensive eye examination is crucial for diagnosing and managing dry eye disease, as it involves a thorough assessment of the patient's symptoms, medical history and various objective tests. Therefore, it is essential to emphasise the importance of proper eye check-up practices, including a comprehensive examination and evaluation of dry eye disease, to ensure accurate diagnosis and effective management.[43–45]

We reviewed the contributions of this study in terms of geographical and racial variations in the prevalence of SDED and its contributing factors. We also assessed key findings from different studies on the prevalence and associated factors of SDED among patients with diabetes.[6–8 25–27 29 31–33 46] The key finding includes the year of publication, study populations, the area of study conducted, associated factors and prevalence of SDED in each study (table 4).

Strengths and limitations of this study

The strength of this study is better generalisability of findings for the diabetic population, achieved through a multicentre study design that includes diverse geographical locations with various study populations and conducted with a sufficient sample size. However, there are certain limitations to consider. This study was conducted by a cross-sectional study design, which restricts the ability to establish causal relationships between dry eye disease and its associated factors. Additionally, potential recall bias may have also influenced the accuracy of self-reported data regarding symptoms and medical history.

CONCLUSIONS

This study indicates a higher prevalence of SDED among patients with diabetes. Factors such as poor glycaemic control, prolonged duration of diabetes, peripheral neuropathy, proliferative diabetic retinopathy and inadequate eye care practices were significantly associated with SDED. Based on these findings, we recommend that improving glycaemic control and promoting regular eye check-ups could help prevent the occurrence of SDED in patients with diabetes.

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Patient consent for publication Consent obtained directly from patient(s).

Ethics approval Ethical clearance was obtained from the University of Gondar College of Medicine and Health Sciences, School of Medicine ethical review committee and the ethical approval number was SOM/622/2023. After briefing the purpose of the study, written informed consent was obtained from each study participant during data collection and all participants. Participants with SDED were linked to an eye clinic for further examination and follow-up. Finally, we declare that the study was conducted under the principles of the Declaration of Helsinki. Participants gave informed consent to participate in the study before taking part.

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