Prevalence and distribution of dry eye disease among patients with type 2 diabetes in Kosovo

Drilon Zekaj,[1,2] Naim Jerliu,[1,3] Floriana Kukaj-Zekaj,[4] Ali Tonuzi[5,6]

[1]Faculty of Medicine, University of Prishtina, Kosovo; [2]Eye Clinic, Clinical University Center of Kosovo, Prishtina, Kosovo; [3]National Institute of Public Health of Kosovo, Prishtina, Kosovo; [4]Eye Clinic "Optika Syri", Drenas, Kosovo; [5]Ophthalmology Service, University Hospital Center "Mother Theresa", Tirana, Albania; [6]Medical University of Tirana, Albania

Correspondence: Naim Jerliu, Faculty of Medicine, University of Prishtina "Hasan Prishtina", Str. Instituti Shëndetësor, n.n., 10 000 Prishtina, Kosovo.
E-mail: naim.jerliu@uni-pr.edu

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ABSTRACT

This study aimed to assess the prevalence and selected correlates of dry eye disease (DED) among patients with type 2 diabetes in Kosovo. A case-series study was conducted in Kosovo from July 2023 to July 2024, including a consecutive sample of 400 patients with type 2 diabetes aged ≥18 years seeking healthcare services at the Eye Clinic of the Clinical University Center of Kosovo in Prishtina (51% females; overall mean age: 62.4±9.7 years; response rate: 80%). Data collection consisted of a detailed clinical examination and a structured questionnaire. Almost 70% of the patients had DED (standalone or combined with retinopathy, which, in turn, had a separate prevalence of 3%). Significant positive correlates of autonomous and/or combined DED and retinopathy included older age, unhealthy dietary patterns, sedentary lifestyle, high blood pressure, and treatment of diabetes with insulin and pills. Our findings indicate a high prevalence of DED among type 2 diabetes patients in Kosovo. DED and retinopathy were strongly associated with a range of demographic factors, behavioral characteristics, and preexisting conditions pertinent to type 2 diabetes patients in this population.

Introduction

According to the Report of the Definition and Classification Subcommittee of the International Dry Eye Workshop (2007), "dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface…".[1] Hence, as a disturbance of the lacrimal functional unit recognized by the Dry Eye Workshop in 2007,[1,2] dry eye disease (DED) causes symptoms of pain and blurry vision, which, for advanced stages of this condition, may pose significant discomfort among the affected patients.[2-4]

Type 2 diabetes is a contributing risk factor for DED development.[3,5-8] DED symptoms might vary between diabetic and non-diabetic patients, but many symptoms are common in both groups, consisting of a persevering feeling, pain, blurred vision, photophobia, itching, hyperemia, and burning.[3,5] The cause of diabetes-related DED has been linked to dysfunction in the lacrimal function unit, due to the effects of hyperglycemia, leading to tear hyperosmolarity and instability of the tear film.[3,5,7]

Overall, DED is a common reason for visits to eye clinics or hospitals, with a high prevalence of 5% to 50% in popula-

tion-based surveys.[5,9,10] However, it should be noted that the wide prevalence ranges reported in the literature before 2017 (*i.e.*, before the Tear Film and Ocular Surface Society Dry Eye Workshop II report in 2017, which contributed to establishing a consensus approach for DED diagnosis) may have been affected by the lack of standardized diagnostic criteria for DED.[5,9]

Kosovo is a middle-income country in the Western Balkans, emerging as the newest state in Europe in 2008 after a prolonged and destructive conflict with Serbia.[11] Since gaining independence, Kosovo has been experiencing a rapid transformation and has implemented significant reforms across all sectors, including the healthcare system.[11] Kosovo has a population of around 1.8 million inhabitants, whose overall life expectancy is about 76.7 years.[12,13] Notably, life expectancy in Kosovo is lower than the neighboring Albania and most of the countries in the Southeastern European region.[14] Similar to most of the countries in the region, noncommunicable diseases are on the rise in Kosovo, with around 22% of the adult population (individuals aged ≥18 years) reporting a chronic disease in 2017.[12,13] Cardiovascular diseases constitute the leading cause of the overall burden of disease (mortality and morbidity combined), followed by cancer and respiratory diseases.[12] Furthermore, the prevalence of diabetes prevails in the population of Kosovo,[12,15] along with unhealthy behaviors including a sedentary lifestyle, overweight and obesity, or inadequate fruit and vegetable intake.[15]

On the other hand, the information about the prevalence and correlates of DED in the population of Kosovo is scant, including patients who seek health services in different health facilities throughout the country.

In this framework, our study aimed to assess the prevalence and distribution of DED among patients with type 2 diabetes in Kosovo. We hypothesized a higher prevalence of DED among older patients and those with hypertension and/or other established risk factors.

Materials and Methods

A case-series study was conducted in Kosovo from July 2023 to July 2024, including a sample of 400 patients with diabetes seeking healthcare services at the Eye Clinic of the Clinical University Center of Kosovo in Prishtina, the capital.

Study population

The minimum required sample size was estimated at 340 participants for various hypotheses related to the association of DED with demographic factors (age), behavioral characteristics (dietary patterns), and preexisting conditions (hypertension and diabetes treatment). However, we decided to invite 500 consecutive patients to participate to increase the study power and take into consideration the potential nonresponse.

From July 12, 2023, to July 1, 2024, 500 consecutive patients with type 2 diabetes aged ≥18 years who showed up at the Ophthalmology Department of the Clinical University Center in Prishtina were invited to participate in this study. Of these, 76 individuals (about 15%) refused to participate, whereas 24 patients did not provide complete information to be considered for the statistical analyses. However, there were no significant age and sex differences between patients who participated in the study and those who refused to participate. Ultimately, the study sample consisted of 400 patients with diabetes aged ≥18 years (196 men and 204 women), with an overall response rate of 80% (400/500).

Data collection

For each patient, data collection consisted of a detailed clinical examination and a structured interviewer-administered questionnaire. The clinical examination, performed on all patients, included fundus examination, optical coherence tomography (OCT), Schirmer's test without topical anesthetic, and tear film breakup time (TBUT).[16] The questionnaire consisted of measurement of discomfort employing the Ocular Surface Disease Index (OSDI) questionnaire [a standardized tool used to assess the symptoms and impact of DED on a patient's daily life, with a score ranging from 0 (no eye discomfort at all) to 100 (maximal eye discomfort)],[16-18] along with an assessment of a range of preexisting conditions, behavioral characteristics, and sociodemographic factors.

Results of the OCT, a non-invasive imaging technique used to capture high-resolution, cross-sectional images of the retina and other structures within the eye,[19] were dichotomized in the analysis into "no changes" (well-defined retinal layers, without signs of swelling, thinning, or abnormalities) *versus* "changes". A positive diagnosis of DED was considered if Schirmer's test score was <10.0 mm/5 min, TBUT<10.0 seconds, and OSDI≥13.[16]

Among patients diagnosed with DED, its grade was subsequently categorized into: "mild" (Schirmer's test: 7.0-9.9 mm/5 min, and TBUT: 7.0-9.9 seconds), "moderate" (Schirmer's test: 5.0-7.0 mm/5 min, and TBUT: 5.0-7.0 seconds), and "severe" (Schirmer's test: <5.0 mm/5 min, and TBUT: <5.0 seconds).[16]

The diagnosis of retinopathy was based on fundus examination (presence of microaneurysms, hemorrhages, hard exudates, cotton-wool spots, neovascularization, or retinal edema) and OCT (presence of macular edema and/or fluid accumulation between the retinal layers and the extent of swelling).[20] In the analysis, the type of retinopathy (among patients who were diagnosed with this condition), was dichotomized into: "non-proliferative diabetic retinopathy (NPDR)" *versus* "proliferative diabetic retinopathy (PDR)".[20]

Sociodemographic factors consisted of gender (males *versus* females), age (categorized in the analysis into ≤50, 51-65, and ≥66 years), place of residence (urban areas *versus* rural areas), profession (categorized into "white collar" occupations, "blue collar" jobs, "housekeepers", and "retired").

Behavioral characteristics included physical activity (categorized into an ordinal scale: "low", "average", and "high" levels), unhealthy dietary patterns ("yes" *versus* "no"), and smoking and/or excessive alcohol intake (also dichotomized into "yes" *versus* "no").

Anthropometric measurements included self-reported height and weight, based on which the body mass index (BMI) was calculated for each participant and expressed in kg/m^2 (in the analysis, trichotomized into: "normal weight", "overweight", and "obesity").

Preexisting conditions and management of diabetes included the presence of high blood pressure ("yes" *versus* "no") and treatment of type 2 diabetes ("pills", "insulin", and "pills and insulin").

Ethical aspects

The study was approved by the Commission for Ethical Issues of the Medical Chamber of Kosovo (decision: 127/2023, date: 07-07-2023). All patients were informed about the aim and objectives of the study and were explained in sufficient detail, particularly the aspects related to the anonymity of the survey and the successive aggregated analysis.

Statistical analysis

Fisher's exact test was used to compare the distribution of background characteristics (demographic factors, anthropometric indices, behavioral factors, and preexisting conditions) between male and female patients included in this study (Table 1).

Likewise, Fisher's exact test was employed to compare the prevalences of different types of eye diseases between men and women (Table 2).

Conversely, binary logistic regression was used to assess the associations of the main outcome (dependent) variables with covariates (Table 3). Initially, logistic regression models were run with "DED, or retinopathy, or both" introduced as the outcome/dependent variable (left panel). Subsequently, logistic regression models were run with "DED, or retinopathy and DED" entered as the outcome variable (right panel). For both outcome variables, the odds ratios (ORs) and their respective 95% confidence intervals (95%CI) and p-values were calculated for each covariate (including demographic factors, anthropometric indices, behavioral factors, and pre-existing conditions).

A p-value of ≤0.05 was considered statistically significant for all statistical tests conducted. Statistical Package for the Social Sciences (SPSS, version 19.0, IBM, Armonk, NY, USA) was used for all the statistical analyses.

Results

Overall, the mean age of the patients was 62.4±9.7 years (63.57±9.73 in men *versus* 61.32±9.60 in women).

Table 1. Distribution of background characteristics in a consecutive sample of patients with diabetes in Kosovo in 2023-2024 (n=400) .

Sociodemographic characteristics	Total (n=400)	Males (n=196)	Females (n=204)	p†
Age				0.025
≤50 years	45 (11.3)*	14 (7.1)	31 (15.2)	
51-65 years	186 (46.5)	91 (46.4)	95 (46.6)	
≥66 years	169 (42.3)	91 (46.4)	78 (38.2)	
Total	400 (100.0)	196 (100.0)	204 (100.0)	
Place of residence				0.333
Urban areas	185 (46.3)	88 (44.9)	97 (47.5)	
Rural areas	215 (53.8)	108 (55.1)	107 (52.5)	
Profession				<0.001
Retired	74 (18.5)	48 (24.5)	26 (12.7)	
Housekeeper	95 (23.8)	2 (1.0)	93 (45.6)	
Blue collar	111 (27.8)	83 (42.3)	28 (13.7)	
White collar	120 (30.0)	63 (32.1)	57 (27.9)	
BMI				0.005
Normal weight	51 (12.8)	20 (10.2)	31 (15.2)	
Overweight	258 (64.5)	142 (72.4)	116 (56.9)	
Obesity	91 (22.8)	34 (17.3)	57 (27.9)	
Physical activity				0.004
Low	46 (11.5)	23 (11.7)	23 (11.3)	
Average	235 (58.8)	100 (51.0)	135 (66.2)	
High	119 (29.8)	73 (37.2)	46 (22.5)	
Smoking and/or excessive alcohol consumption				0.097
No	287 (71.8)	133 (67.9)	154 (75.5)	
Yes	113 (28.2)	63 (32.1)	50 (24.5)	
Unhealthy diet				0.999
No	376 (94.0)	184 (93.9)	192 (94.1)	
Yes	24 (6.0)	12 (6.1)	12 (5.9)	
High blood pressure				0.207
No	137 (34.3)	61 (31.1)	76 (37.3)	
Yes	263 (65.8)	135 (68.9)	128 (62.7)	
Diabetes treatment				0.792
Pills	298 (74.5)	146 (74.5)	152 (74.5)	
Insulin	36 (9.0)	16 (8.2)	20 (9.8)	
Pills and insulin	66 (16.5)	34 (17.3)	32 (15.7)	

BMI, body mass index; *absolute numbers and their respective column percentages (in parentheses); †p-values from Fisher's exact test.

Background characteristics of study participants

Overall, more than 2 in 5 patients (about 42%) were 66 years and older, and almost 1 in 2 (around 47%) were 51-65 years. Male patients were significantly older than female patients (proportion of individuals aged ≥66 years: approximately 46% *versus* 38%, respectively; p=0.03). Slightly more than 1 in 2 patients (about 54%) were rural residents, a demographic characteristic that was almost similarly distributed among males and females. Regarding the profession, almost 1 in 4 patients (24%) were housekeepers, 30% reported white collar occupations, whereas around 28% reported blue collar jobs. As expected from a traditional society such as Kosovo, there was a highly statistically significant difference (p<0.01) in the distribution of professional categories between male and female patients (about 46% of women reported to be housekeepers compared to only 1% of men). Overall, only about 13% of study participants had a normal weight (10% of men and 15% of women), whereas the prevalence of obesity in this sample of patients with diabetes was almost 23% (17% in men *versus* 28% in women, p<0.01). The prevalence of a sedentary lifestyle was almost similar in men and women (about 11-12%), whereas a high level of physical activity was significantly more prevalent in men than in women (37% *versus* 23%, respectively; p<0.01). Overall, about 28% of the patients reported smoking and/or excessive alcohol consumption (32% in men *versus* 25% in women, p=0.10). Only 6% of the patients with diabetes reported unhealthy dietary habits, a behavioral characteristic that was very similarly distributed among men and women. Almost two-thirds of the patients (about 66%) had high blood pressure, without significant gender differences. As for the treatment of diabetes, about three-quarters of the patients (almost 75%) reported the use of pills for the management of this chronic condition, whereas almost 17% of them reported the use of both pills and insulin, without evidence of any significant gender differences (Table 1).

Prevalence of different types of eye diseases among study participants

Almost 1 in 2 patients (45%) exhibited OCT changes, which was significantly more prevalent in men compared to women (about 54% *versus* 37%, respectively; p<0.01). The prevalence of standalone DED in this sample of Kosovo patients with type 2 diabetes was 33% (around 30% in men *versus* 36% in women). Furthermore, almost 37% of participants had both DED and retinopathy (43% in men *versus* 31% in women, p<0.01). Conversely, the prevalence of retinopathy alone was 3% (5% in men *versus* only 1% in women). The cumulative prevalence of DED and retinopathy was almost 73% (about 78% in men *versus* 68% in women; p=0.04). Almost 70% of the patients had DED (standalone or combined with retinopathy), without evidence of gender differences. As for the grade of DED, about 30% of the patients exhibited a mild degree, 35% a moderate degree, and 5% a severe degree (without any gender differences). Regarding the retinopathy type, 37% of the patients had NPDR (45% in men *versus* 29% in women; p<0.01) and almost 3% had PDR (Table 2).

Correlates of dry eye disease

In binary logistic regression models with "DED, or retinopathy, or both" as the outcome variable (Table 3 – left

Table 2. Prevalence of different types of eye diseases in the study population (n=400).

Variable	Total (n=400)	Males (n=196)	Females (n=204)	p†
OCT				0.001
No changes	219 (54.8)*	91 (46.4)	128 (62.7)	
Changes	181 (45.3)	105 (53.6)	76 (37.3)	
Diagnosis				0.003
None	109 (27.3)	44 (22.4)	65 (31.9)	
DED	132 (33.0)	58 (29.6)	74 (36.3)	
Retinopathy	12 (3.0)	10 (5.1)	2 (1.0)	
Both	147 (36.8)	84 (42.9)	63 (30.9)	
Diagnosis				0.043
None	109 (27.3)	44 (22.4)	65 (31.9)	
DED, or retinopathy, or both	291 (72.8)	152 (77.6)	139 (68.1)	
Diagnosis				0.277
None, or retinopathy	121 (30.3)	54 (27.6)	67 (32.8)	
DED, or retinopathy and DED	279 (69.8)	142 (72.4)	137 (67.2)	
DED grade				0.385
Normal eyes	121 (30.3)	54 (27.6)	67 (32.8)	
Mild	118 (29.5)	59 (30.1)	59 (28.9)	
Moderate	141 (35.3)	70 (35.7)	71 (34.8)	
Severe	20 (5.0)	13 (6.6)	7 (3.4)	
Retinopathy type				0.004
None	241 (60.3)	102 (52.0)	139 (68.1)	
NPDR	148 (37.0)	88 (44.9)	60 (29.4)	
PDR	11 (2.8)	6 (3.1)	5 (2.5)	

OCT, optical coherence tomography; DED, dry eye disease; NPDR, non-proliferative diabetic retinopathy; ODR, proliferative diabetic retinopathy; *absolute numbers and their respective column percentages (in parentheses); †p-values from Fisher's exact test.

panel), there was evidence of positive association with male gender (OR=1.6, 95% CI=1.0-2.5). Furthermore, there was a graded positive relationship with age, with older patients (66 years and above) exhibiting a significantly higher risk compared with their youngest counterparts (OR=8.3, 95% CI=4.0-17.2). In addition, "DED, or retinopathy, or both" was positively associated with housekeeping (OR=2.2, 95% CI=1.2-4.2) and retirement (OR=2.6, 95% CI=1.3-5.3). Overall, the association with BMI was not statistically significant, notwithstanding a graded positive relationship with overweight and obesity. Conversely, there was a graded and inverse relationship with physical activity, with patients reporting a sedentary lifestyle exhibiting the highest risk for "DED, or retinopathy, or both" (OR=3.6, 95% CI=1.4-9.3). Notably, "DED, or retinopathy, or both" was strongly and positively associated with unhealthy dietary habits (OR=4.4, 95% CI=1.0-18.9). Also, there was a strong and significant association with high blood pressure (OR=3.2, 95% CI=2.0-5.1). Furthermore, treatment of diabetes with insulin and pills was strongly and positively related to "DED, or retinopathy, or both" (OR=4.1, 95% CI=1.8-9.4). On the other hand, there was no significant association with place of residence, smoking and/or excessive alcohol consumption (left panel).

In binary logistic regression models with "DED, or retinopathy and DED" as the outcome variable (Table 3 – right panel), there was no evidence of a significant association with gender. On the other hand, there was evidence of positive relationships of "DED, or retinopathy and DED" with the following correlates: older age (OR=8.9, 95% CI=4.3-18.5), housekeeping profession and retirement (OR=2.4, 95%

Table 3. Association of main outcomes with background characteristics of the patients. Results from binary logistic regression models.

Variables	Left panel "DED, or retinopathy, or both" *versus* "None"			Right panel "DED, or retinopathy and DED" *versus* "None, or retinopathy"		
	OR*	95% CI*	p*	OR	95% CI	p
Sex						
Women	1.00	reference	0.035	1.00	reference	0.250
Men	1.62	1.03-2.53		1.29	0.84-1.97	
Age			<0.001 (2)†			<0.001
(2)						
≤50 years	1.00	reference	-	1.00	reference	-
51-65 years	4.13	2.09-8.17	<0.001	4.20	2.10-8.39	<0.001
≥66 years	8.29	4.01-17.2	<0.001	8.90	4.28-18.5	<0.001
Place of residence						
Rural areas	1.00	reference	0.750	1.00	reference	0.507
Urban areas	1.07	0.69-1.67		0.87	0.56-1.33	
Profession			0.013 (3)			0.003 (3)
White collar	1.00	reference	-	1.00	reference	-
Housekeeper	2.23	1.19-4.18	0.012	2.43	1.33-4.46	0.004
Blue collar	1.27	0.73-2.19	0.402	1.38	0.81-2.36	0.239
Retired	2.62	1.29-5.31	0.007	2.96	1.49-5.88	0.002
BMI			0.120 (2)			0.332 (2)
Normal weight	1.00	reference	-	1.00	reference	-
Overweight	1.84	0.98-344	0.057	1.57	0.84-2.94	0.153
Obesity	2.02	0.97-4.24	0.062	1.61	0.78-3.32	0.195
Physical activity			0.016 (2)			0.028 (2)
High	1.00	reference	-	1.00	reference	-
Average	1.56	0.97-2.50	0.069	1.38	0.87-2.20	0.172
Low	3.64	1.43-9.28	0.007	3.27	1.35-7.93	0.009
Smoking and/or excessive alcohol intake						
No	1.00	reference	0.843	1.00	reference	0.775
Yes	1.05	0.64-1.72		1.07	0.67-1.73	
Unhealthy diet						
No	1.00	reference	0.048	1.00	reference	0.029
Yes	4.38	1.01-18.9		5.09	1.18-22.0	
Diabetes treatment			<0.001 (2)			<0.001
(2)						
Pills	1.00	reference	-	1.00	reference	-
Insulin	3.92	1.35-11.4	0.012	3.42	1.29-9.07	0.013
Pills and insulin	4.13	1.82-9.38	<0.001	3.09	1.52-6.31	0.002
High blood pressure						
No	1.00	reference	<0.001	1.00	reference	<0.001
Yes	3.22	2.04-5.09		3.01	1.93-4.70	

DED, dry eye disease; OR, odds ratio; CI, confidence interval; BMI, body mass index; *ORs, 95% CIs and p-values from crude (unadjusted) binary logistic regressions models; †overall p-values and degrees of freedom (in parentheses).

CI=1.3-4.5, and OR=3.0, 95% CI=1.5-5.9, respectively), sedentary lifestyle (OR=3.3, 95% CI=1.4-7.9), unhealthy dietary habits (OR=5.1, 95% CI=1.2-22.0), treatment of diabetes with insulin and pills (OR=3.1, 95% CI=1.5-6.3), and high blood pressure (OR=3.0, 95% CI=1.9-4.7) (Table 3 – right panel).

Discussion

The main findings of this study include a high prevalence of DED, a condition that was present in 70% of the patients, either standalone (33%) or combined with retinopathy (37%). Retinopathy itself had a separate prevalence of 3%. The prevalence of separate DED was somehow higher in women than in men (36% *versus* 30%, respectively), whereas an opposite finding was evident for the combined prevalence of DED and retinopathy (31% *versus* 43%, respectively). Also, the prevalence of retinopathy alone was higher in men than in women (5% *versus* 1%, respectively). Factors that were positively and significantly associated with autonomous and/or combined DED and retinopathy consisted of older age, unhealthy dietary habits, lack of physical exercise, high blood pressure, and treatment of type 2 diabetes with insulin and pills.

The prevalence of DED in our study is comparable with other hospital-based studies or studies conducted in other clinical settings.[5,9,21-23] Hence, a meta-analysis aiming at estimating the prevalence of DED in Africa has reported a prevalence of about 39% (95% CI=22-57%) in hospital-based studies,[21] which is comparable with our estimate on the prevalence of standalone DED (33%). According to this meta-analysis, there was no evidence of significant associations between DED and sex,[21] which is somehow compatible with our findings on the standalone prevalence of DED (36% in women *versus* 30% in men), but not with its combined prevalence with retinopathy (31% in women *versus* 43% in men), for which this meta-analysis does not inform about. Furthermore, our findings on the combined prevalence of DED and retinopathy among type 2 diabetes patients (70%) are in line with a fairly recent study conducted among diabetes patients where the prevalence of combined DED was reported at 64%.[5]

Conversely, the prevalence of standalone DED in our study (33%) is comparable also with a study conducted in Brazil including diabetes patients, where the prevalence of DED was reported at about 38%.[22] Also, according to this study,[22] the prevalence of DED was significantly higher among older diabetic patients, which is compatible with our findings. Additionally, our findings on the separate prevalence of DED are in line with a previous report from Ozdemir *et al*.,[23] whereas Hom and De Land have reported a higher DED prevalence (53%), but their study was based on a self-reported instrument only.[24] On the other hand, the prevalence of DED reported from a Chinese study is lower (about 18%) than our estimate, but this was a community-based study including diabetes patients who may have had a milder disease.[25]

The association of diabetes with DED has been well documented in many studies.[3,5,9,26,27] Also, a positive association between DED occurrence and duration of type 2 diabetes has been documented.[5,9,28] Future studies in Kosovo should investigate the link between the duration of type 2 diabetes and DED. Otherwise, our findings on positive associations between DED and older age, unhealthy behaviors, high blood pressure, and type of diabetes treatment are generally compatible with previous reports from the international literature.[3,5,9,22]

This study may have some limitations, including the sample representativeness, the possibility of information bias, and the study design. We recruited patients seeking services at the Eye Clinic of the Clinical University Center of Kosovo in Prishtina. However, patients showing up at this tertiary center may not necessarily represent all patients with type 2 diabetes in Kosovo, which may jeopardize the generalizability of the study findings. Furthermore, regardless of the validity and reliability of the measuring instruments employed in our study, the self-reported information through the structured questionnaire may be subject to information bias. Also, the study design does not allow to judge the presence of causal relationships.

Nonetheless, far beyond the abovementioned potential limitations, this study provides useful evidence on the extent and distribution of DED among type 2 diabetes patients in the population of Kosovo. Of note, this is one of the very few reports on DED in the populations of Albanian-speaking populations in the Western Balkans region.

Conclusions

Our findings indicate a high prevalence of DED among type 2 diabetes patients in Kosovo, a country in the Western Balkans characterized by an intensive process of political and socioeconomic transformations. DED and retinopathy were strongly associated with a range of demographic factors, behavioral characteristics, and preexisting conditions pertinent to patients with type 2 diabetes in this population.

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