PREVALENCE AND FACTORS ASSOCIATED WITH RELATED DIABETES MELLITUS OCULAR DAMAGE IN TUNISIA. Short running title: Diabetes mellitus ocular damage characteristics

Prévalence et facteurs associés aux lésions oculaires liées au diabète sucré en Tunisie.

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ABSTRACT

Introduction: Our study aimed to assess the prevalence and the factors associated with ocular damage caused by diabetes mellitus. **Methods:** This transversal study was carried out at department C of the National Institute of Nutrition of Tunis, in collaboration with the ophthalmology unit of the same institution and the ophthalmology department of the Charles Nicolle Hospital of Tunis. patients. 300 patients were include had an exhaustive ophthalmological examination to assess diabetes-related ocular damage. **Results:** The mean age was 53.7±16.3 years. The sex ratio was 0.65. The mean duration of diabetes was 11.16 years ± 7.02 years. The mean HbA1C was 10.51 ± 2.35%. The mean time to first screening for diabetic retinopathy (DR) was 4.44 years. The prevalence of DR was 41%. It was proliferative and complicated in 32.3% and 2.3% of cases respectively. Refractive disorders (16%) were myopia (0.04%), hyperopia (9%), and astigmatism (9%). No patients had oculomotor disorders. Dry eye syndrome was common in 6.7%. The main factors associated with diabetes-related eye damage were diabetes duration, glycemic imbalance, micro and macrovascular complications, hypertension, and dyslipidemia. **Conclusion:** Diabetic retinopathy had a high prevalence in our population. Improving glycemic balance and implementing retinal imaging, reachable and easy to perform, are essential.
Keywords: Diabetes mellitus, HbA1C, Diabetic retinopathy, Cataract, Blindness, Fundus.

RESUME

Introduction : Notre étude visait à évaluer la prévalence et les facteurs associés aux lésions oculaires causées par le diabète. Méthodes : Cette étude transversale a été menée au sein du département C de l'Institut National de Nutrition de Tunis, en collaboration avec le service d'ophtalmologie du même établissement et le service d'ophtalmologie de l'hôpital Charles Nicolle de Tunis. Trois cents patients ont été inclus et ont bénéficié d'un examen ophtalmologique complet afin d'évaluer les lésions oculaires liées au diabète. Résultats : L'âge moyen était de 53,7 ± 16,3 ans. Le sex-ratio était de 0,65. La durée moyenne du diabète était de 11,16 ± 7,02 ans. Le taux moyen d'HbA1c était de 10,51 ± 2,35 %. Le délai moyen avant le premier dépistage de la rétinopathie diabétique (RD) était de 4,44 ans. La prévalence de la RD était de 41 %. Elle était prolifférative dans 32,3 % des cas et compliquée dans 2,3 % des cas. Les troubles de la réfraction (16 %) étaient la myopie (0,04 %), l'hypermétropie (9 %) et l'astigmatisme (9 %). Aucun patient ne présentait de troubles oculomoteurs. Le syndrome de l'œil sec était fréquent (6,7 %). Les principaux facteurs associés aux lésions oculaires liées au diabète étaient la durée du diabète, le déséquilibre glycémique, les complications micro- et macrovasculaires, l'hypertension et la dyslipidémie. Conclusion : La rétinopathie diabétique était très fréquente dans notre population. Il est essentiel d'améliorer l'équilibre glycémique et de mettre en place un examen d'imagerie rétinienne accessible et facile à réaliser. Mots-clés : Diabète sucré, HbA1c, rétinopathie diabétique, cataracte, cécité, fond d'œil.

INTRODUCTION

Diabetes mellitus is a chronic metabolic disease with galloping prevalence worldwide and in Tunisia (1,2). Its course could be complicated with micro and macroangiopathic complications. The eye is one of the organs particularly affected. Many eye damages could be seen, each with different pathophysiology, presentation, and management, but all could threaten vision.

Diabetic Retinopathy (DR) is the most common and serious eye damage caused by diabetes. Currently, it is a real public health problem affecting 4.2 million people worldwide and this frequency continues to increase (3, 4). It represents one of the main causes of blindness in the working-age population worldwide (5). DR onset increases the longer the diabetes has been evolving. Its evolution is also influenced by the diabetes balance, the presence of high blood pressure and access to care (6).

It may evolve for long time without any symptoms. Indeed, visual acuity remains preserved for a long time, while DR continues to evolve silently. Over time, chronic

hyperglycemia damage blood vessels especially those of the retina. Blood circulation become defective and novel vessels grow up to substitute damaged one. However, these novel vessels bleed easily and could leak exudative fluid resulting in vision problems and serious complications. Then, we assist to significant health and economic impact and substantially altered quality of life in these patients.
Early diagnosis can stop evolution and delay serious complications leading to blindness (7,8). In early stages of DR, a tight control of diabetes, dyslipidemia and blood pressure are the recommended measures to stop progression to advanced stages.
This outlines the value of screening and early treatment, and highlights the role of the multidisciplinary team in managing those patients and reducing morbidity of diabetic eye disease.
Few Tunisian studies have focused on diabetes ocular complications and their associated factors, Therefore, we conducted this study to determine the prevalence and factors associated with ocular damage caused by diabetes mellitus.

METHODS

1- Type and location of the study: This was a descriptive cross-sectional study carried out at Department C of Nutrition and therapeutic dietetics of the National Institute of Nutrition and Food Technologies of Tunis, in collaboration with the ophthalmology unit of the same institution, and the ophthalmology department of the Charles Nicolle hospital in Tunis.

2- Studied population:

2.1. Sample size: The sample size was calculated on the basis of a 95% confidence interval, and a prevalence of DR in Tunisia estimated at 26.3% according to the study by Kahloun et al [9]. The minimum sample required was 298, according to the following formula:
$n=(z)^2p(1-p)/d^2$ (n=sample size, z=1.96 for a confidence level of 95%, p=estimated proportion of the population with DR, d= tolerated error margin at 5%).
Thus, we randomly included 300 patients among those hospitalized for poorly controlled diabetes.

2.2. Inclusion and non-inclusion criteria: We included patients aged over 18 who consented to participate in our study. We did not include pregnant women with diabetes.

3-Study protocol

3.1-Data collection: Each patient underwent a clinical examination to collect age, gender, habits, pathological history, ophthalmological history, diabetes type and duration, current antidiabetic treatment and degenerative complications (Myocardial Infarction (MI), Transcient ischemic attack (TIA), Obliterating Arteritis of the Lower Limbs (OALL), Chronic Renal Failure (CKD) ...), weight, height and blood pressure. We calculated the body mass index (BMI) according to the formula:
BMI (kg/m^2) = Weight (kg) / $height^2$ (m^2).
Likewise, after 12 hours of fasting, we dosed fasting blood sugar (measured by glucose oxidase enzymatic method, "Beckman" kit on a Beckman DXC600 analyzer), HbA1C (measured by the ion exchange HPLC technique on a Tosoh G8 analyzer), cholesterol, triglyceridemia and HDLemia, creatininemia (measured by the Jaffé method, “Beckman” Kit on a Beckman DXC600 analyzer) and 24-hour microalbuminuria.
LDL-cholesterol was calculated by the Friedewald formula. Creatinine clearance was estimated by the CKD-EPI formula.
The ophthalmological examination was bilateral, complete, before and after dilation. Before dilation, it included: The measurement of visual acuity, coupled with the study of refraction, carried out separately for each eye, far and near, using a decimal scale subsequently converted into log Mar for far and near vision. Parinaud scale was used for near vision.
Oculomotricity was evaluated by the examination of the fixation in primary position, the analysis of voluntary ocular motility in the nine directions of gaze, the study of the quality of fixation in extreme gaze movements and the convergence analysis.
The anterior segment was examined using the slit lamp, before dilation, to assess dry syndrome, with an evaluation of the tear film breakup time (BUT) after instillation of fluorescein, and an analysis of the fixation of the dye on the cornea and the conjunctiva.
The measurement of tonometry, correlated with pachymetry, was made using an air tonometer. If the measurement was greater than 22 mm Hg, a second measurement with the Goldmann applanation tonometer was done.
A gonioscopy was done to examine iridocorneal angle. An examination of the anterior chamber was performed.
After pupil dilation with 0.5% tropicamide, the examination included: An evaluation of lens' transparency, cataract's type and extent, fundus examination, done eye by eye with the slit lamp, using a non-contact Superfield type lens. The examination of the fundus included an analysis of the macular region, the papilla and the peripheral retina. The use of a green filter facilitated early detection of new vessels and other vascular abnormalities. Several classifications of DR have been proposed in the literature. In our study, we used the Wilkinson International classification of the American Ophthalmological Society of 2003 (8). The

choice of this classification was guided by its ophthalmoscopic nature allowing the classidfication of the different stages of DR. Indeed, we were not able to perform fluorescein angiography and OCT in our study due to their unavailability in the institution.
Patients were divided into two groups according to diabetes duration:
-Group 1 (G1): Diabetes duration <10 years.
-Group 2 (G2): Diabetes duration ≥10 years.
3-2-Statistical analysis: Data entry and analysis were carried out using SPSS 21.0 software. The variables were described by a central tendency indicator (proportion and mean) and by a dispersion indicator (standard deviation). Comparisons between quantitative variables were made using the analysis of variance test or the Student t test, and in case of invalidity by the nonparametric Mann-Whitney test.
Comparisons between qualitative variables were carried out using Pearson's X^2 (Chi-square) test and, in the case of invalidity of this test, using Fisher's two-sided exact test. The significance threshold retained was 0.05. To determine the risk factors for DR, we performed a multivariate analysis by logistic regression.
4-Ethical considerations: This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. We explained the aims and the protocol study for each eligible patient. All eligible patients signed consent to participate. This study was carried out with respect of medical confidentiality and patient anonymity. The ethics committee of the National Institute of Nutrition of Tunis approved this study on February 2020.

RESULTS:
1. Population characteristics and comorbidities: Characteristics and comorbidities of the population are detailed in Table 1.
2-Results of the ophthalmological examination of the population: The results of the ophthalmological examination are recorded in Table 2.
3-Factors associated with DR characteristics and its severity in multivariate analysis: The factors associated with DR characteristics and its severity in multivariate analysis have been detailed in Table 3.

DISCUSSION
Diabetes mellitus (DM) is a no communicable disease of concern actually, with alarming rates worldwide and in Tunisia (1,2). Obesity, sedentarily life styles and high-energy diets have resulted in its growing burden in all countries. DM results in significant morbidity, increases premature mortality rate and impacts negatively life quality via its cascading micro and macroangiopathic complications. Ocular damages caused by DM are serious health problems which dramatically threaten patients with diabetes. Then, prevention and early management seem to be essential in this leading cause of preventable blindness among working-age population. However, this still be challenging especially in developing countries. This lead as to focus on the case of Tunisia.
1-Visual acuity: According to a meta-analysis of 259 studies, patients with DM are 25 times more at risk of developing blindness compared to the general population (10). Likewise, according to the WHO, DR is responsible for 4.9% of cases of blindness worldwide (11). In Tunisia, visual impairment due to DR increased by 20% in 2016 (12).
In our study, visual acuity was significantly lower in cases of long-standing diabetes. This result could be explained by high prevalence of advanced-stages DR. According to the Gallice et al study, nearly 10% of patients with DM suffer from blurring vision after 15 years of DM (13).
In our study, the rate of blindness, defined by the absence of light perception, was 2.7%. This is a high rate compared to The EURODIAB IDDM Complications Study and Klein et al study (14-15).
Higher mean age in our population is plausible to explain this result. High rate of cecity (4.4%) was also shown in another tunisian study (16).
2- Prevalence and factors associated with diabetic retinopathy: DM and its degenerative complications are expanding worldwide resulting in significant health, social, economic and professional repercussions (17).
In our study, 41% (n=123) had DR. It was proliferative in 8.7% of cases. This result is probably underestimated given that retina's examination was not possible in patients with cataract. However, it is a high prevalence which could be explained by the location of the study, conducted at a level 3 university-hospital-center, where patients often have long-standing and complicated diabetes.
Some European studies have reported lower prevalences than ours. This could be explained by further access to care. Arab (18, 19) and african (20, 21) studies have reported similar results to ours.
Factors associated with DR were age, long-standing DM, HbA1C, basal insulin dose>1 IU/Kg/d, neuropathy, nephropathy, stroke and TIA. Factors associated with DR severity were age, long-standing DM and nephropathy.
Screening for DR was not effective enough in our population. It was done after 4 years on average after DM diagnosis. Then, ocular damage occurs and progress silently and reachs advanced stages.
In Voight et al study, almost half of the population had a documented screening for DR in their medical records (22). Some authors,

including Porta et al. suggest systematic screening every two years in type 2 DM instead of annual screening, to compensate for the lack of resources (23).

3-Refractive disorders: Refractive disorders were not associated with DR in our study. Some studies showed that that myopia could be protective against DR (24, 25).

4-Sicca syndrome: Sicca syndrome prevalence was 6.7%. It were more frequent in long-standing DM without reaching the threshold of significance. Sicca syndrome could be an autonomic complication of DM characterized by tear deficiency secretion (26).

5-Oculomotor disorders: Ophthalmoplegia is a rare complication of DM. Its prevalence varies from 1 to 14% [27]. The most common disorder is binocular diplopia. It is associated with glycemic imbalance and with DR (28). In our study, we did not find any oculomotor disorder. However, the Tunisian study by Lajmi et al. had shown a fairly high frequency of these disorders (28).

6-Caractat: Cataract is the leading curable cause of blindness worldwide (29, 30). It is frequently associated with T2DM (31, 32, 33). Indeed, accumulation of sorbitol induces hyperosmolarity and water infusion into the lens. Thus, liquefaction of the lens fibers sets in, inducing its opacification (34, 35).

30,7% of our population had cataract. It was significantly associated with age, DM duration, nephropathy and diabetic neuropathy.

In a Korean study cataract was present in half of the population (36). Caird et al. showed that 10,7% of patients operated on for cataract had DM (37). Klein et al found an incidence of cataract surgery of 8,3% in T1DM and 24,9% in T2DM (38). A systemic review of the literature published in 2019 concluded that there was a significant positive association between cataract age and glycemic balance (39).

7-Intraocular pressure disorders: Eight per cent of the population had ocular hypertonia without significant association with DM duration. Our results were consistent with the study of Lavaju et al which did not show a correlation between open-angle glaucoma and diabetes duration (40).

Strong points and limitations: The sample size analyzed in our study, which was representative of the general population, the exhaustive ophthalmological examination, and the assessment of care access and its impact on DR frequency and progression, were the main strong points of our study.

Indeed, to our knowledge, it is a pioneer study in Tunisia with extrapolable results that could serve as a basis for an effective preventive strategy in our developing country.

However, it was a monocentric study carried out in the national institute of nutrition of Tunis, which is a third level hospital structure, where patients are usually with poor glycemic control and cumulating comorbidities and degenerative complications. Moreover, it was not possible to evaluate macular odema due to lack of Optical coherence tomography (OCT) in our institution.

CONCLUSIONS

Diabetes mellitus induced ocular damages are leading cause of blindness worldwide. Prevention and early detection are acknowledged as a key in delaying serious problems and vision loss in patients with DM.

In fact, patients with diabetes mellitus should benefice of a holistic management in order to rule out related DM ocular damages. DM must be tight balanced. All metabolic and hemodynamic abnormalities which could aggravate DM ocular damages should be controlled. Then dyslipidemia and hypertension, as the most frequently associated comorbidities of DM, should be screened and treated. Moreover, promoting healthy lifestyle patterns, including good dietary habits, regular physical activity, and cigarette and alcohol cessation are useful to slow up ocular damages development.

All of these measures could be implemented in a national program, based on multidisciplinary approach including first line general practitioners who should learn to do retinographs witch could be analyzed by ophthalmologists thanks to telemedicine. Optical coherence tomography (OCT) use should be more accessible so that macular edema is regularly assessed and treated. Reference centers must be defined to drain patients with ocular complications or those who need further investigations. This simplify the patient course, reduces care access problems and guarantees homogenous care.

Such a well-designed program would substantially impact public health in our country and limits economic burden of related DM ocular damages.

The authors declare not to have any conflict of interest.

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Table 1: Population characteristics and comorbidities

	Population (n=300)	**G1 (n=154)**	**G2 (n=146)**	**p**
Mean Age (Years):	53.7 ± 16.3	48.2 [14-88]	56.5 [15-85]	<0,001
Sex ratio:	0,65	0,69	0,62	0,53
Smoking (% (n)):	42 (126)	23 (69)	19 (57)	0,07
Hypertension (% (n)):	41,7 (125)			
Dyslipidemia(% (n)): Hypercholestérolemia: Hypertriglycéridemia: Mixed dyslipidemia:	61 (183) 53,3 (160) 4,7 (14) 3 (9)	34 (102) 29,7 (89) 2,6 (8) 1,7 (5)	27 (81) 23,7 (71) 2,1 (6) 1,3 (4)	0,1 0,1 0,24 0,2
Mean Weight (Kg):	75,2±15.8	72.4±12.1	75.8±8.2	0,3
Mean height (cm):	162±9	160±6	168±4	0,1
Mean BMI (Kg/m²):	27.98±6.23	28,3±6.92	26.6±4.21	0,55
Type of Diabetes: T1DM: % (n) T2DM: % (n)	 19,3 (58) 80,7 (242)	 9 (27) 42,3 (127)	 10,3 (31) 38,4 (115)	 0,21 0,09
DM duration (Years):	11.16 ans ± 7.02	6.2± 3.41	14.73 ± 5.12	$<10^{-3}$
Treatment: OAD (% (n)): Insulin therapy+OAD (% (n)):	 45,9 (111) 43,7 (131)	 29,6 (72) 10,3 (31)	 16,3 (39) 33,3 (100)	 0,03 0,02
FBG (mmol/L):	9,7	8,9	10,54	0,02
HbA1c (%):	10,51	10,14	10,69	0,04
Peripheral diabetic neuropathy (% (n)):	40 (120)	8 (24)	32 (96)	0,03
Diabetic nephropathy (% (n)):	20,7 (62)	5,3 (16)	15,4 (46)	0,05
Microalbuminuria (% (n)):	14,3(43)	5 (15)	9,3 (28)	0,02
Macroalbuminuria (% (n)):	6,3 (19)	0,3 (1)	6 (18)	10^{-3}
Coronary insuffisciency (% (n)):	10,7 (32)	5 (15)	5,7 (17)	0,01
Arteritis (% (n)):	16,3 (49)	6,6 (20)	9,7 (29)	0,03
Stroke (% (n)):	4,3 (13)	1,6 (5)	2,7 (8)	0,7
Transcient ischemic attack (% (n)):	1,7 (5)	0	5 (1,7)	0,1

Table 2: Results of the ophthalmological examination of the population

	Population générale (n=300)	G1 (n=154)	G2 (n=146)	p
Blindness (% (n)):	2,66 (8)	0	2,66 (8)	
Visual acuity (*) of the right eye (log mar) (mean, standard deviation):	0,1664 ±0,24322	0,1048 ±0,18934	0,2343 ±0,27640	<0,001
Decimal visual acuity of the right eye:	7/10	8/10	6/10	
Visual acuity (*)of the left eye (log mar) (mean, standard deviation):	0,1743 ±0,26098	0,0961 ±0,17421	0,2575 ±0,30863	
Decimal visual acuity of the left eye:	7/10	8/10	5/10	
DR (% (n)) (PDR/ NPDR) (%)):	41 (123) (8,7/32,3)	12 (36) 0,6/11,4)	29 (87) (8/21)	$<10^{-3}$ 0,004
Time to first screening for DR (Years) (**):	4,44 ans ± 4,98	3,66 ±3,98	5,12 ±4,7	0,01
Time to first screening for DR according to the type of DM (T1DM/T2DM) (Years):	(214) 2,1 ±1,25/ 5,04 ±3,41 (p=0,001)	(20/80) 2,01 ± 1,12/ 4,58 ± 2,17	(24/90) 2,17 ± 1,48/ 5,54 ± 1,97	0,01 0,01
Time to first screening for DR according to the presence of DR (Absence of DR/Presence of DR):	3,79±4,63/5,09±5,27 (p=0,013)	-	-	-
Time to first screening for DR according to the severity of DR (Minim NPDR / Mild NPDR /Sever NPDR /PDR) (Years):	4,1±3,27/4,87±4,22/ 4,91±3,41/7,87±6,23 (p<0,001)	-	-	-
DR complications (%(n)):	2,3 (7)	0,3 (1)	2 (6)	0,002
Intravitreal hemorrhage:	0,3 (1)	0	0,3 (1)	0,03
Retinal detachment:	1,7 (5)	0	1,7 (5)	0,01
Neovascular glaucoma:	0,3 (1)	0,3 (1)	0	0,01
Sicca syndrome (% (n)):	6,7 (20)	2,7 (8)	4 (12)	0,66
Cataract (%):	37 (111)	10,7 (32)	26,3 (79)	<0,001
Mean intraocular pressure (mm Hg) (Ocular hypertonia (% (n))):	15,38 ± 3,3 (8(24))	15,36 ±3,5 5 (15)	15,42 ± 2,8 3 (9)	<0,001 0,1
Refractive disorders (% (nn)) (***):				
Myopia:	4 (12)	2,3 (7)	1,7 (5)	0,42
Hyperopia:	9 (27)	5,7 (17)	3,3 (10)	0,14
Astigmatism:	9 (27)	4,7 (14)	4,3 (13)	0,55
Troubles oculomoteurs (% (n)):	0,3 (1)	0	0,3 (1)	-

*: Visual acuity was significantly lower in case of proliferative DR (OD=7/10; OG=7/10 in case of non proliferative DR, versus: OD=4/10; OG=5/10 in case of proliferative DR, p <0.001).
**: 214 (71.3%) patients answered.
***: We did not find a significant association between refractive error and DR.

Table 3: Factors associated with DR characteristics and severity, and with cataract in multivariate analysis

	Presence of DR:	Severity of DR:	Presence/Absence of cataract:
Age (p, OR [95% IC])	**0,005** **0,96** **[0.92 - 1.01]**	**0,05, 1,23** **[0.92 - 1.52]**	57±7.51; 51±4.2 **p<0,001**
Gender:	0,5, 0,83 [0.42 - 1.61]	0,8, 0,82 [0.05 - 1.43]	-
Diabetes duration (≥ 10 ans):	**<0,001** **1,19** **[1.06 - 1.2]**	**0,003, 1,16** **[1.05 - 1.2]**	26,3 (79)/ 22,3 (67) **<0,001**
FBG:	0,4, 1,42 [0.77 - 1.85]	-	11,9; 8,7 **0,02**
HbA1C:	**1.004, 09** **[0.86 - 1.17]**	0,9, 0,99 [0.78 - 1.21]	11± 2.32; 10.30 ± 2.33 **0,012**
Basal insulin dose >1 UI/kg/j:	**0,03, 5,98** **[1.4 - 8.79]**	0,8, 1,27 [0.13 - 9.8]	-
Diabetic peripheral neuropathy:	**0,001, 2,4** **[1.4 - 4.2]**	0,9, 1,04 [0.4 - 2.6]	22,3 (67)/ 17,7 (53) **<0,001**
Diabetic nephropathy:	**<0,001, 7,8** **[3.8 - 12.9]**	**0,004, 3,8** **[1.5 - 9.5]**	10,7 (32)/10 (30) **0,001**
Coronary insuffisciency:	0,08, 2,7 [0.88 - 3.4]	0,5, 1,42 [0.45 - 4.3]	6 (18)/ 4,7 (14) p=0,07
Arteritis:	0,7 1,78 [0.82 - 3.8]	0,8, 0,91 [0.32 - 2.7]	8,3 (25)/ 8 (24) p=0,3
Stroke:	**0,03, 5,9** **[1.18 - 9.2]**	0,3, 1,8 [0.47 - 7.4]	2,7 (8)/ 1,7 (5) p=0,2
Transcient ischemic attack:	**0,01, 5,14** **[1.74 - 15.1]**	0,4, 1,35 [0.93 - 2.96]	0,7 (2)/ 1 (3) p=0,13
Hypertension:	0,6, 0,87 [0.47 - 1.6]	0,6, 0,81 [0.31 - 2.19]	-
Dyslipidemia:	0,3, 1,31 [0.73 - 2.3]	0,3, 1,92 [0.51 - 6.6]	-
Time to first screening for DR:	**0,01, 1,46** **[1.07 - 1.99]**	**0,02, 1,12** **[1.02 - 1.34]**	-