http://rjdnmd.org
Rom J Diabetes Nutr Metab Dis. **26**(4):425-434
doi: 10.2478/rjdnmd-2019-0045

ASSESSMENT OF COMMON RISK FACTORS AND LIFESTYLE HABITS ASSOCIATED WITH ATHEROGENIC RISK AND LIPID-LOWERING THERAPY IN MEN WITH TYPE 2 DIABETES

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received: November 06, 2019 *accepted*: December 14, 2019
available online: February 01, 2020

Abstract

Background and aims: *Our objective was to determine common risk factors and lifestyle habits associated with atherogenic risk and with the use of lipid-lowering therapy in men with type 2 diabetes.* ***Material and Methods:*** *A comparative cross-sectional study was performed in the northwestern Algeria during eleven months on adult men patients with type 2 diabetes. Anthropometric parameters, blood pressures and lipid profile were evaluated. Data of common risk factors and lifestyle habits associated to atherosclerosis were compared between two groups according to the lipid lowering therapy use based on statins.* ***Results:*** *147 adult men patients with type 2 diabetes were involved in the study, 68 (46.26%) were under statins therapy and 79 (53.74%) were not. Significant associations with statins use were observed regarding the age group of 61-70 years (OR: 0.156 [0.043-0.570]; p=0.005), a salary of less than 30000 Algerian dinars (≈250.60$) (OR: 5.758 [1.299-25.512]; p=0.021), age of diabetes of 2-3 years (OR: 0.105 [0.013-0.867]; p=0.036) as well as with lipid ratios and body mass index (BMI). However, no significant associations were noted regarding the other studied parameters (marital status, educational level, occupation, salary, and family history, smoking status, alcohol consumption and sports practices) with lipid lowering therapy.* ***Conclusion:*** *Age of patients, diabetes duration, lipid ratios and the low income of patients are the strongest factors associated with the use of lipid lowering therapy (statins). However, largest longitudinal studies are needed to determine whether modifiable lifestyle habits could influence the lipid lowering therapies prescription in diabetic patients over time.*

key words: *type 2 diabetes, lipid-lowering therapy, lifestyle habits, atherogenic risk, statins*

Background and aims

The epidemic of diabetes mellitus and its related complications poses a worldwide health threat. Data suggest that the burden of diabetes continues to increase in most countries, which is often interpreted as evidence of increasing risk in the population. However, selective incidence studies and some evidence of risk factors that follow suggest the opposite [1-3]. In 2015, the International Diabetes Federation (IDF) estimated that 1 in 11 adults worldwide aged 20 to 79 years had diabetes mellitus (about 415

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million adults). This estimate is expected to increase to 642 million adults by 2040, with the largest contribution from countries with low-income to middle-income levels [4].

Type 2 diabetes (T2D) is now recognized as a pandemic and a significant risk factor for cardiovascular disease (CVD) and peripheral vascular disease especially in the presence of other common risk factors, such as smoking, hypertension, male gender and dyslipidemia [5]. The higher risk of atherosclerosis in type 2 diabetic patients consists of several factors. Diabetic dyslipidemia as one of the key factors that intensify the risk of CVD in diabetics, is characterized by high levels of plasma triacylglycerol, low concentration of high-density lipoprotein (HDL) cholesterol, and increased concentration of small-dense particles of low-density lipoprotein (LDL) [6].

The management of dyslipidemia is majorly based on LDL-cholesterol lowering therapy with the use of statins as treatment of choice for CVD prevention. A significant reduction in cardiovascular events has been observed in a large number of large-scale, randomized and clinical trials on LDL reducing therapies [7].

Although the associated complications of T2D are often responsible of important rates of morbidity and mortality, it is a preventable disease. To control the diabetes disease, it is essential to determine associated risk factors [8]. The uncontrollable factors consist of socioeconomic status, age, sex, genetic predisposition, family history and other environmental factors. However, controllable risk factors include anthropometric characteristics such as obesity and waist circumference, life style habits, hypertension, dyslipidemia, and smoking status [9].

The main purpose of the present study is to assess common risk factors associated to the atherosclerosis-related cardiovascular diseases by comparing two groups of male adult patients suffering from type 2 diabetes treated or not with statins as a preliminary lipid-lowering therapy.

Material and method

Framework of the study and selection of patients

A comparative cross-sectional study was carried out at the level of the public establishment of local health (Larbi BEN M'HIDI Diabetes Center) in the *Wilaya* of Sidi-Bel-Abbes located in the northwestern Algeria. The investigation lasted for 11 months (September, 2018 to July, 2019). Male patients, aged between 35 and 75 years, with confirmed type 2 diabetes (for less than 10 years) coming for medical consultation according to a pre-established schedule have been solicited to participate in the study. Authorizations were obtained from the director of the Public Establishment of the Proximity Health of the *Wilaya* of Sidi-Bel-Abbes and the chief of the Antidiabetic Centre, in order to perform the study. Excluding criteria were used in order to reduce confounding effects on the studied parameters; female gender, hypothyroidism, renal impairment, liver dysfunction and patients already operated on for cardiovascular complications as well as patients with non-communicable diseases and patients with a motor or mental disability.

The study population was divided into two groups: a group of T2D patients treated with statins, as a preliminary lipid-lowering therapy, and a comparative group of T2D patients not treated with statins.

Questionnaire data

Data were collected through a face-to-face interview with patients using a well-detailed questionnaire includes questions on socio-economic status, lifestyle, marital status,

education level, food hygiene, smoking and alcohol consumption, the duration of diabetes, periodic medical consultation, medical treatment and physical activity. The average time allocated to each patient was 30 minutes.

Anthropometric measurements

The anthropometric parameters were measured in the morning on patients with a minimum of clothing and without shoes by taking care of the instructions of the World Health Organization (WHO) [10]. The weight and height parameters were measured using a digital column scale with height measuring rod (TCS-200-RT: max: 200kg, d: 100g, min: 2kg).The weight and height measurements of each patient were used to calculate the body mass index (BMI) as follows: BMI = weight (Kg)/ height^2 (m^2). Waist circumference was measured using a plastic tape (max: 150 cm, graduation length: 1mm) at the line with the navel.

Blood pressure measurement

Blood pressure was measured using a manual sphygmomanometer and stethoscope (Riester, Jungingen Germany). An average mean of three measurements was considered for each patient.

Biochemical parameters

From patients' medical records, the results of the latest analysis of blood were taken namely; fasting glycaemia, glycated hemoglobin (HbA1c), total cholesterol TC), high density lipoprotein cholesterol (HDL-c), low density lipoprotein cholesterol (LDL-c) and triglycerides (TG). Furthermore, lipid ratios as indicators of atherogenic risk were calculated; TC/HDL, LDL/HDL and TG/HDL.

Statistical analysis

Statistical analyses were processed using the SPSS statistical software version 22.0 [11]. Number and percentage were calculated for qualitative variables and means ± standard deviations were considered for quantitative variables. However, Odds Ratios (OR) with a confidence interval of 95% were calculated to assess risk factors associated to the lipid lowering therapy prescription. Student *t*-test was employed to compare quantitative variables and Chi-square test for comparing qualitative variables. A *p* value of less than 0.05 was considered statistically significant.

Results

Table 1 summarises the comparison of basic characteristics of participants. 147 adult men patients with confirmed type 2 diabetes were included in this study. Amongst all patients, 68 (46.26%) were under treatment with cholesterol-lowering therapy based on statins and 79 (53.74%) were not. Using Chi-square test, higher significant effect (p=0.002) of age group difference was found between the two groups of diabetic patients (treated *vs.* not treated with statins). The age group of 61-70 years was the most frequent in patients treated with statins; however, the 50-60 years group was for patients non-treated with statins. All the same, significant effect (p=0.038) of age of diabetes was recorded between the two groups of diabetic patients treated *vs.* non-treated with statins. Nevertheless, no significant influences were noted for the other studied parameters (marital status, educational level, occupation, salary, family history and sports practices) between the two groups of patients.

Table 2 displays the comparison of anthropometric characteristics, blood parameters and life style habits between type 2 diabetic patients treated or not with statins. The age of

patients treated with statins was significantly higher (p=0.005) comparing to those non-treated. Likewise, regarding the anthropometric parameters, the body weight (p=0.020) and the BMI (p=0.037) were significantly higher in patients treated with statins. When analysing the diet characteristics of our patients, the frequency of fast-food consumption was significantly higher in patients who were not under statins therapy comparing to the statin users.

Table 1. Comparison of demographic and socio-economic characteristics between cases (treated with statins) and controls (not treated with statins)

Variables	Group treated with statins (n=68)		Group non treated with statins (n=79)		p value
	Count	%	Count	%	
Age (In years)					0.002
<50	8	11.8	10	12.6	
50-60	16	23.5	41	51.9	
61-70	34	50.0	24	30.4	
>70	10	14.7	4	5.1	
Marital Status					0.224
Single	1	1.5	6	7.6	
Married	65	95.5	71	89.9	
Widowed	1	1.5	0	0.0	
Divorced	1	1.5	2	2.5	
Educational level					0.052
Illiterate	10	14.7	8	10.1	
Primary	8	11.8	19	24.1	
Middle	9	13.2	20	25.3	
Secondary	20	29.4	14	17.7	
High	21	30.9	18	22.8	
Occupation					0.261
Jobless	4	5.9	11	13.9	
Employed in the state sector	13	19.1	17	21.5	
Employed in the private sector	6	8.8	4	5.1	
Independent job	8	11.8	14	17.7	
Retired	37	54.4	33	41.8	
Salary (in Algerian dinars)					0.110
Without	3	4.4	10	12.6	
<30000	24	35.3	27	34.2	
30000-50000	22	32.4	30	38.0	
50000-100000	19	27.9	11	13.9	
>100000	0	0.0	1	1.3	
Age of diabetes (In years)					0.038
<1	4	5.9	9	11.4	
1-2	1	1.5	8	10.1	
2-3	5	7.4	9	11.4	
3-4	3	4.4	7	8.9	
>4	55	80.9	46	58.2	
Family history of diabetes					0.218
No one	26	38.2	38	48.1	
Father	11	16.2	10	12.7	
Mother	18	26.5	18	22.8	
Both of parents	6	8.8	11	13.9	
Not mentioned	7	10.3	2	2.5	
Sport practices					0.523
Yes	45	66.2	53	67.1	
No	23	33.8	26	32.9	

p value for Chi-square test, p<0.05 was considered as statistically significant.

Our results about the comparison of arterial blood pressure, blood parameters, lipid ratios, smoking status, alcoholism and physical activity did not reveal any significant differences between the patients treated and those non-treated with statins.

Table 2. Comparison of anthropometric characteristics, blood parameters and life style habits between type 2 diabetic patients treated or not with statins.

Variables		Group treated with statins (n=68)	Group non treated with statins (n=79)	*p* value
Age of patients (in years)		61.89±8.61	58.10±7.68	0.005#
Anthropometric parameters				
Height (m)		1.72±0.06	1.71±0.05	0.810#
Weight (kg)		84.75±13.54	79.67±12.33	0.020#
Waist circumference (cm)		108.33±10.48	105.46±8.95	0.078#
BMI (kg/m^2)		28.59±4.16	27.07±4.44	0.037#
Arterial blood pressure				
Diastolic blood pressure (mmHg)		131.7±21.8	124.7±15.0	0.245#
Systolic blood pressure (mmHg)		63.8±10.5	61.1±11.9	0.437#
Blood tests results				
HbA1c (%)		7.29±0.98	8.75±2.80	0.117#
TC (g/l)		1.52±0.63	1.60±0.53	0.789#
HDL-c (g/l)		0.37±0.06	0.36±0.08	0.850#
LDL-c (g/l)		0.80±0.46	0.88±0.30	0.703#
TG (g/l)		1.71±1.16	1.44±0.61	0.550#
Lipid ratios				
TC/HDL		4.31±2.45	4.00±0.66	0.771#
LDL/HDL		2.30±1.65	2.35±0.57	0.933#
TG/HDL		5.10±2.27	3.48±1.84	0.382#
Smoking status				
Smoker (%)		7.35	11.39	0.405*
Ex-smoker (%)		67.64	36.29	0.740*
Non-smoker (%)		25.01	52.32	0.041*
Beginning age of active smoking for smokers and ex-smokers (in years)		28.00±16.85	20.37±13.29	0.382#
Age of smoking cessation for ex-smokers (in years)		39.74±11.96	37.95±10.32	0.447#
Active smoking duration for smokers and ex-smokers (in years)		20.39±13.65	18.33±10.72	0.432#
Number of cigarettes per day for smokers and ex-smokers		22.14±20.12	19.63±11.99	0.448#
Number of packets of cigarettes per day for smokers and ex-smokers		1.70±1.08	1.26±0.51	0.055#
Alcohol consumption				
Alcohol drinker (%)		--	--	--
Ex-alcohol drinker (%)		41.17	30.37	0.172*
Non-alcohol drinker (%)		58.82	69.62	0.214*
Age of alcoholism cessation for ex-drinkers (in years)		35.36±11.73	32.38±9.05	0.395#
Active alcoholism duration for ex-drinkers (in years)		14.16±1.20	12.37±0.99	0.623#
Diet characteristics				
Frequency of meals per day		3.53±0.78	3.51±0.67	0.848#
Taking snakes (%)	*Yes*	19.1	25.3	0.369*
	No	80.9	74.7	
Eating fast food (%)	*Yes*	13.4	27.8	0.034*
	No	86.6	72.2	
Physical activity				

Practice of physical activity (%)	*Yes*	66.2	67.1	0.907*
	No	33.8	32.9	
Frequency of practicing physical activity (%)	*Everyday*	81.8	84.9	0.777*
	Every week	7.0	3.8	
	Occasionally	11.6	11.3	

(#) *p* value for student *t* test; (*) *p* value for Chi-square test; $p<0.05$ was considered as statistically significant; BMI: body mass index; HbA1c: glycated haemoglobin; TC: total cholesterol; HDL: high-density lipoproteins; LDL: low-density lipoprotein; TG: triglycerides.

Table 3. Multivariate logistic regression displaying crude association of mean risk factors associated with statins use.

Variables	Unadjusted OR (95% CI)	*p* value
Age group (In years)		
<50	Reference	--
50-60	0.320 [0.072-1.415]	0.133
61-70	0.156 [0.043-0.570]	0.005
>70	0.567 [0.159-2.022]	0.381
Marital status		
Single	Reference	--
Married	0.333 [0.014-8.182]	0.501
Widowed	1.831 [0.162-2.672]	0.625
Divorced	1.323 [0.031-3.164]	0.974
Educational level		
Illiterate	Reference	--
Primary	1.071 [0.349-3.293]	0.904
Middle	0.361 [0.128-1.020]	0.054
Secondary	0.386 [0.141-1.056]	0.064
High	1.224 [0.484-3.100]	0.669
Occupation		
Jobless	Reference	--
Employed in the state sector	2.103 [0.543-8.138]	0.282
Employed in the private sector	4.125 [0.749-22.714]	0.104
Independent job	1.571 [0.374-6.611]	0.538
Retired	3.083 [0.895-10.621]	0.074
Salary (in Algerian dinars)		
No salary	Reference	--
<30000	5.758 [1.299-25.512]	0.021
30000-50000	2.444 [0.601-9.939]	0.212
50000-100000	2.963 [0.729-12.045]	0.129
>100000	1.116 [0.778-2.506]	0.149
Currently smoking status		
Non Smoker	Reference	--
Smoker	1.620 [0.516-5.091]	0.409
Past smoking status		
Non Smoker	Reference	--
Smoker	0.880 [0.414-1.871]	0.740
Alcohol consumption		
No	Reference	--
Yes	0.623 [0.316-1.231]	0.173
Age of diabetes (In years)		
<1	Reference	--
1-2	0.372 [0.107-1.286]	0.118
2-3	0.105 [0.013-0.867]	0.036
3-4	0.465 [0.145-1.484]	0.196
>4	0.358 [0.088-1.465]	0.153
Diabetes treatment		

Diet alone	Reference	--
Oral antidiabetics	0.378 [0.170-0.844]	0.018
Insulin alone	0.193 [0.051-0.725]	0.015
Oral antidiabetics and insulin	2.071 [1.235-3.758]	0.025
Family history of diabetes		
No one	Reference	--
Father	0.314 [0.052-1.882]	0.205
Mother	0.286 [0.052-1.567]	0.149
Both of parents	0.156 [0.024-1.001]	0.050
Hypertension		
No	Reference	--
Yes	0.365 [0.186-0.714]	0.003
Sport practices		
No	Reference	--
Yes	1.042 [0.524-2.072]	0.907
Corpulence		
Normal weight	Reference	--
Overweight	0.375 [0.148-0.948]	0.038
Obese	0.708 [0.313-1.604]	0.408

CI: confidence interval; OR: Odds Ratio.

For the whole study population (Table 3), the crude association of mean risk factors associated with statins use resulted in significant associations regarding the age group of 61-70 years (OR: 0.156; CI 95%: 0.043-0.570; p=0.005), a salary of less than 30000 Algerian dinars (≈250.60$) (OR: 5.758; CI 95%:1.299-25.512; p=0.021), age of diabetes of 2-3 years (OR:0.105; CI 95%: 0.013-0.867; p=0.036). Furthermore, regarding the clinical considerations, significant associations were found with all kind of diabetes treatments (oral antidiabetics and/or insulin alone), with family history of diabetes in "both of parents" (OR: 0.156; CI 95% 0.024-1.001; p=0.050), with hypertension (OR: 0.365; CI 95% 0.186-0.714; p=0.003) and with overweight as one of the corpulence variants (OR: 0.375; CI: 0.148-0.948; p=0.038).

Discussion

People with type 2 diabetes mellitus as an independent risk factor, as well as the common coexisting conditions (hypertension and dyslipidemia), are prone to several cardiovascular events such as atherosclerosis and stroke [12]. In the present study, 53.74% of adult male patients with type 2 diabetes mellitus aged 35 to 75 years were not statin users. Evidences support that the use of statin therapy, as recommended by guidelines, in patients with type 2 diabetes is an indicator of the existence of a preliminary cardiovascular risk [13]. In their study, involving 56,934 patients and based on 18 randomized controlled trials studies, Taylor et al (2013) found that statin therapy reduced all-cause mortality. Similarly, statin therapy reduces the incidence of fatal and nonfatal cardiovascular events, especially cerebrovascular and atherosclerotic events [14,15].

Our findings showed that statins users comparing to those non-treated with statins had significantly higher age, diabetes duration and were categorised in older age groups. This approach is supported by evidence showing that the majority of type 2 diabetic patients are considered at lower risk. However, mostly individuals will attain a higher risk with a long duration of diabetes disease (about 20% over a 20-year period) [13].

In the current study, male T2D patients were more likely to be less educated (illiterate, primary and middle levels) and to have lower monthly salary (<250.60$). Rabi et al (2006)

established the same conclusions [16]. The relationship between income and development of diabetes is complex. It has been speculated that the increased diabetes risk encountered in low income groups is correlated to the increased prevalence of obesity within this group. People with a high income can afford to maintain a healthy lifestyle by buying healthier products and food [17,18]. Likewise, regarding the educational level, it is possible that high-educated patients are advocate for their health and care better of their disease [19].

We demonstrated that the prevalence of T2D was higher in married patients. Our results are in accordance with the consequences of Murad et al (2006) and Qi et al (2019) [8,19]; however, previous findings showed that marital status was not correlated with diabetes development [20].

The comparison of anthropometric characteristics and arterial blood pressure in our study population revealed higher values of body weight, wait circumference, BMI, systolic and diastolic blood pressures in T2D patients under statin therapy comparing to those who were not. Ho et al (2018) reported the same observations; the corpulence parameters and hypertension are significantly correlated to the statins prescription and to their high intensity use [21]. However, other authors suggest that statin therapy reduces subcutaneous fat, usually related to BMI, but not visceral fat (waist circumference) that is significantly associated with CV complications [22,23].

The results of lipid parameters and their ratios indicated high levels of LDL cholesterol in both patients treated with statins (0.80±0.46 g/l) and those non treated (0.88±0.30 g/l), these LDL values suggest a higher cardiovascular risk in T2D population. In addition, TC/HDL, and TG/HDL ratios were higher in both groups thus exceeding the atherosclerosis risk thresholds of 4.0 for both TC/HDL and TG/HDL [24-26]. Nichols et al (2018) established that even with statin therapy, CV event rates were greater among diabetes patients [27].

Our results regarding smoking status, alcohol consumption and physical activity did not reveal any significant difference between the two groups of patients (patients treated with statins or not). These findings are in accordance with conclusions of previous works [21,28]. Furthermore, smoking status was not associated with statin prescription. The finding is consistent with previous literature showing that people continued to smoke despite known adverse health effects. In addition, even non- and ex-smokers treated with statins or not are exposed to passive smoking, which can be a confounding factor since it is difficult to quantify [29,30].

No difference in alcohol consumption between statin-treated and untreated patients. Previous studies have reported conflicting results despite the known effect of alcohol consumption as a CV risk factor. However, there is no consensus on the relationship between alcohol consumption and statin prescription [31].

This study showed no relationship between physical activity and statin prescription. Our results differ from previous studies, which showed that statin-treated patients exercise less physical activity than untreated patients do [32]. In addition, according to a French study, among patients taking statins, several complications were observed (muscle symptoms, symptoms that interfere with daily activities and there were even patients who became bedridden with their symptoms) [33].

There are some limitations to the present study. First, the participation in the study was voluntary and several parameters were self-reported, which may have underestimated or overestimated these factors. Second, the study was done in a single area of Algeria, wherever the time was constrained, however, despite these

inherent limitations, we believe that our conclusions would remain unchanged in the general population. Third, the cross-sectional design does not assess the real causality between prescription of statins and lifestyle, since lifestyle factors may certainly change over time.

Conclusions

In adult male patients suffering from type 2 diabetes, a significant proportion of statin users did not achieve the goals of normal lipid status (especially LDL levels) and threshold of lipid ratios (atherosclerosis risk indices), compared with patients not treated with statins, which means that the risk of cardiovascular complications still persists.

Statin users had higher body weight, waist circumferences and BMI, higher blood pressures and blood lipid ratios. However, there was no difference in smoking status, physical exercise levels or alcohol consumption, as life style factors, between statin users and non-users after adjusting for clinically important covariates. Longitudinal studies are needed to determine whether possible lifestyle modifications among statin users are sustained over time.

Acknowledgements. The authors express their heartfelt thanks to the LBM Diabetes Center staff as well as all the patients who participated in this study.

Conflict of interest. No conflict of interest is to declare.

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