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ORIGINAL ARTICLE

Lipid Profile Disorders and Diabetic Foot Risk; Is There A relationship between Them?

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ABSTRACT

Background: Diabetic dyslipidemia is characterized by elevated fasting, postprandial triglycerides (TGs), low high-density lipoprotein (HDL), and elevated low-density lipoprotein (LDL). This study aimed at assessing frequency of dyslipidemia among patients with diabetes, identifying risk factors for potential dyslipidemia and defining its relation with diabetic foot risk.

Methods: A cross-sectional study involved 345 patients with type 2 diabetes mellitus attending Diabetes outpatient clinic, Zagazig University hospital from March to September 2019. The studied patients underwent history taking, physical examination emphasizing on foot examination and laboratory investigations including lipid profile, and glycosylated hemoglobin (HbA1c).

Results: Mean patients' age was 50.34 years. Male constituted 58.3%. About 86% , 42%, 44.1% had middle social class, comorbid hypertension, and uncontrolled diabetes respectively. Dyslipidemia prevailed in 41.4%. About 20.3% had low diabetic foot risk. There were significant relation between occurrence of dyslipidemia and all of diabetes control, cigarette smoking, comorbid hypertension, body weight, BMI, fasting blood glucose (FBG), and diabetic foot risk. Increasing body weight non-significantly elevated risk of dyslipidemia by about one fold. Rising duration of diabetes, fasting blood glucose, uncontrolled diabetes, and presence of comorbid hypertension significantly increased that risk by about one, one, five, two and seven folds respectively. Dyslipidemia significantly increased risk of intermediate, high and very high risk for diabetic foot by three, 6.15 and 6.42 folds respectively.

Conclusion: Dyslipidemia was prevalent in diabetic patients. Increasing duration of diabetes, (FBG), uncontrolled diabetes, comorbid hypertension were significant risk factor for dyslipidemia. Dyslipidemia significantly increased diabetic foot risk.

Keywords: Risk, foot, dyslipidemia**.**

INTRODUCTION

Dyslipidemia is an increase in plasma cholesterol, TGs, both or presence of reduced level HDL-cholesterol [1]

Independently of TG levels and other risk factors a link is established between reduced HDL-cholesterol levels and augmented cardiovascular risk [2]

The principal pathophysiology of diabetic dyslipidemia is both complex and not well understood. Hypertriglyceridemia, low HDL-cholesterol and a predominance of small dense LDL can be detected years before the clinical diagnosis of type-2 diabetes in insulin-resistant, prediabetic individuals with normal glucose concentrations [3]

Diabetic dyslipidemia could be originated from defects of insulin secretion and subsequent hyperglycemia. Moreover, the obesity and insulin-resistant state lead to development of dyslipidemia irrespective of hyperglycemia [4]

International Diabetic Federation (IDF) released a diabetic foot risk stratification paradigm. Such guidelines targets at protecting the diabetic foot from breakdown, ulceration and further lower limb

amputations. This can be achieved by adopting early preventative measures and managing the foot in the early Risk Categories of 1, and 2 before inflowing the very high Risk Category [5]

This study aimed at assessing frequency of dyslipidemia among patients with diabetes, identifying risk factors for potential dyslipidemia and defining its relation with diabetic foot risk.

PATIENTS AND METHODS

Study design and Setting: A cross-sectional study was conducted in Diabetes outpatient Clinic in Zagazig University hospital from March to September 2019.

Study participants:

Inclusion criteria: Adult patients with type 2 diabetes of both genders

Exclusion criteria: Patients having hepatic, renal, other metabolic disorders or other comorbidities other than hypertension.

Sample size and technique: Sample size was calculated using Open Epi to be 320 with addition of 10% to compensate for potential non-response; hence the total sample was 352 patients with confidence level 95% and power of 80% as total number of patients with diabetes attending to Diabetes outpatient Clinic in Zagazig University hospital was 2000 patients/6 months and prevalence of diabetic dyslipidemia is 55% [6]. A systematic random method was adopted for patient selection. Sampling interval was 2000/352 so each sixth patient who met inclusion criteria was selected

Case definition: Dyslipidemia was defined as lipid profile that consists of the following abnormalities either singly or in combination. These include TC ≥200 mg/dL, and/or TG levels ≥150 mg/dL, [8]

Uncontrolled diabetes included those who had HbA1c≥7% according to American diabetic association 2019 [9].

IDF 2017 Risk stara [5] Strata were highlighted in (Table 1)

Study Tools:

*I.**Interviewing Questioners***

All Participating patients were subjected to the following:

Socioeconomic level was assessed using updated scale of ElGilany et al. [7]. Scores<50% is considered as low standard, 50-<75% as middle class while≥75% consided as high class

Detailed history taking about onset, duration of diabetes, type of drug used.

II. **Full clinical *Examination.***

General and local examination.

Vital signs, Upper, lower limbs and head and neck examination with comment on lymph nodes.

Foot examination: inspection of skin for infection, ulceration or blistering. Musculoskeletal examination for deformity. Neurological assessment using 10 g monofilament and 4 vibration using 128-Hz tuning fork pinprick sensation and ankle reflexes. Vascular assessment for foot pulses

III. **Laboratory tests:**

Blood samples were withdrawn to measure Fasting glucose, lipid profile, Glycated hemoglobin (HbA1c) was measured on EDTA blood by ion-exchange resin method. Urine analysis.

Field work: All Participating patients were interviewed to collect demographic data, personal data, detailed history taking. This interview took about 20 minutes each patient. Then all patients underwent thorough clinical examination with assessment of diabetic foot risk according to IDF risk stratifications. Patients were asked to return the next morning for blood collection in overnight (≥8 h) fasting state. Blood samples were withdrawn to measure Fasting glucose, lipid profile, Glycated hemoglobin (HbA1c). Urine samples were collected for analysis was performed to all patients to detect sugar and acetone in it

Administrative design and ethical standards: The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

An official permission was obtained from institutional review board (IRB) of faculty of Medicine, Zagazig University and directors of outpatient clinic and head of department of internal medicine department. Written informed consent was obtained from all participants.

Statistical methods: The collected data were coded and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 25.0, IBM Corp., Chicago, USA, 2017. Continuous variables were expressed as mean ± Standard deviation (SD), median and range while the categorical variables were expressed as a number (percentage). Continuous variables were checked for normality by using Shapiro wilk test. All normally distributed data were analyzed using Independent Student t (t) test. Multivariate logistic regression was carried out to identify the risk factors that are independently associated with single and mixed dyslipidemia. Significance was set at $p<0.05$. p value ≤0.001 is considered statistically highly significant

RESULT

Only 345 patients completed the study. Age of the studied patients ranged from 20 to 69 years with mean 50.34 years. Male constituted 58.3%. About 43% and 42% were mild and low social class.

About 40% were smokers, 42% had comorbid hypertension, and 44.1% had uncontrolled diabetes. Mean BMI was 30.43 kg/m^2 ranged from 17.51 to 38.87 kg/m^2. Fasting blood glucose falls in the range from100 to 442 mg/dL. Regarding glycosylated hemoglobin, it ranged from 5.59 to 15.9 with mean 8.21. Disease duration ranged from 1 to 25 years with mean 6.65 years. Concerning lipid profile, mean total cholesterol, triglycerides, LDL, HDL cholesterol were 184.54, 168.14, 122.09 and 48.94 mg/mL (Table 2).

Using IDF stratification of diabetic foot among the patients; 20.3% had low risk while 13%, 23.5% and 43.2% had intermediate, **high** and very high risk respectively (Table 2)

About 11% of patients abnormally low HDL cholesterol. Abnormally high (borderline to high and high levels collectively) total cholesterol, LDL cholesterol and triglycerides were prevalent in 37.1 %, 42.9% and 44.1% respectively (Table 3). Dyslipidemia (defined as having abnormally high total cholesterol, triglycerides or both) was found in 41.4%.

There were statistically significant relation between diabetes control and all of total cholesterol, HDL, LDL cholesterol, triglycerides and overall dyslipidemia. In any type, uncontrolled patients had significantly abnormal levels (Table 4).

Statistically non-significant difference was found between occurrence of dyslipidemia and either gender, age, social class or patients' height. There were statistically significant relation between occurrence of dyslipidemia and all of cigarette smoking, comorbid hypertension, body weight, BMI and fasting blood glucose. Male gender, smokers, having comorbid hypertension increased risk of dyslipidemia by 1.4, 2.62 and 4.07 folds respectively. Both low and middle social class were non-significant protectors (Table 5).

Multivariate analysis of risk factors of dyslipidemia:

Increasing body weight non-significantly elevated risk of dyslipidemia by about 1 fold. Rising duration of diabetes, fasting blood glucose, uncontrolled diabetes, and presence of comorbid hypertension significantly increased that risk by about one, one, five, two and seven folds respectively (Table 6).

Relation between dyslipidemia and diabetic foot risk:

There is significant relation between dyslipidemia and diabetic foot risk where high and very high risk were prevalent in dyslipidemic patients. Using low risk as reference category, dyslipidemia significantly increased risk of intermediate, high and very high risk for diabetic foot by 3, 6.15 and 6.42 folds respectively (Table 7)

Table (1) IDF 2017 Risk stara [5] Strata

Risk category 0	Risk category 1	Risk category 2	Risk category 3
Normal plantar sensation	Loss of protective sensation (LOPS)	LOPS+ high pressure or poor circulation or structural deformities or onchomycosis	History of ulceration, amputation or neuropathic fractures
Low risk	Intermediate risk	High risk	Very high risk

Table (2) Distribution of the studied (345) patients according to demographic characteristics and special habits:

Variables	N=345	%
Gender:		
Male	201	58.3
Female	144	41.7
Socioeconomic level:		
Low	146	42.3
Middle	148	42.9
High	51	14.8
Smoking:		
Non-smoker	208	60.3
Smoker	137	39.7
Comorbid hypertension:		
Absent	200	58
Present	145	42
Diabetic control:		
Controlled (HbA1c≤7)	193	55.9
Uncontrolled (HbA1c>7)	152	44.1
IDF Risk strata of diabetic foot:		

Variables	N=345	%
Low risk	70	20.3
Intermediate	45	13
High risk	81	23.5
Very high risk	149	43.2
	Mean ± SD	**Range**
Age (years)	50.34 ± 10.65	20 - 69
BMI (kg/m^2)	30.43 ± 4.64	17.51 – 38.87
Body weight (kg)	83.74 ± 10.94	50 - 113
Height (m)	1.66 ± 0.1	1.51 – 1.88
Fasting blood glucose (mg/dl)	176.46 ± 61.93	100 - 442
HbA1c	8.21 ± 2.54	5.59 – 15.9
Disease duration (years)	6.65 ± 3.95	1- 25
Serum total cholesterol (mg/dl)	184.54 ± 42.25	130 - 280
LDL cholesterol (mg/dl)	1242.09 ± 42.19	60 – 200
HDL cholesterol (mg/dl)	48.94 ± 8.01	30 – 70
Serum triglycerides (mg/dl)	168.14 ± 59.74	90 – 400

IDF: international diabetic federation HbA1c: Glycosylated hemoglobin BMI: Body mass index LDL: Low density lipoprotein HDL: High density lipoprotein

Table (3) Distribution of the studied (345) patients according to dyslipidemia:

	N=345	%
Dyslipidemia:		
Absent	202	58.6
Present	143	41.4
Cholesterol level:		
Normal	217	62.9
Borderline to high	47	13.6
High	81	23.5
Triglycerides level:		
Normal	193	55.9
Borderline to high	66	19.1
High to very high	86	24.9
LDL cholesterol:		
Normal	197	57.1
Borderline to high	60	17.4
High to very high	88	25.5
HDL cholesterol:		
Normal	306	79.4
Low **(<40)**	39	11.3

LDL: Low density lipoprotein HDL: High density lipoprotein

Table (4) Relation between diabetic control and presence of dyslipidemia among the studied (345) patients:

Lipid profile	Total	Uncontrolled	controlled	p#
	N=345	**N=152(%)**	**N=193(%)**	
Dyslipidemia:				
Absent	202 (58.6)	49 (24.3)	153 (75.7)	<0.001**
Present	143 (41.4)	103 (67.8)	40 (20.7)	
Cholesterol level:				
Normal	217 (62.9)	54 (24.9)	163 (75.1)	<0.001**
Borderline to high	47 (13.6)	34 (72.3)	13 (27.7)	
High	81 (23.5)	64 (79.0)	17 (21.0)	
Triglycerides level:				
Normal	193 (55.9)	64 (33.2)	129 (66.8)	<0.001**

Lipid profile	Total	Uncontrolled	controlled	p#
	N=345	N=152(%)	N=193(%)	
Borderline to high	66 (19.1)	27 (40.9)	39 (59.1)	
High to very high	86 (24.9)	61 (70.9)	25 (29.1)	
LDL cholesterol:				
Normal	197 (57.1)	49 (24.9)	148 (75.1)	
Borderline to high	60 (17.4)	39 (65.0)	21 (35.0)	<0.001**
High to very high	88 (25.5)	64 (72.7)	24 (27.3)	
HDL cholesterol:				
Normal	306 (88.7)	191 (94.6)	115 (81.4)	<0.001**
Low **(<60)**	39 (11.3)	11 (5.4)	28 (19.6)	
Diabetic foot risk:				
Low risk	70 (20.3)	10 (14.3)	60 (85.7)	
Intermediate risk	45 (13.0)	21 (46.7)	24 (53.3)	<0.001**
High risk	81 (23.5)	41 (50.6)	40 (49.4)	
Very high risk	149 (43.2)	80 (53.7)	69 (46.3)	

**p≤0.001 is statistically highly significant LDL: Low density lipoprotein HDL: High density lipoprotein
#Chi square for trend test

Table (5) Relation between dyslipidemia and the studied parameters among the (345) patients:

Parameter	Dyslipidemia			p#	COR (95% CI)
	Total	Present	Absent		
	N=345(%)	N=143(%)	N=202(%)		
Gender:					
Male	175 (42.1)	72 (41.4)	85 (58.6)	0.129	1.4 (0.91-2.15)
Female	188 (57.9)	71 (37.7)	117 (62.3)		
SES:					
Low	146 (41.6)	62 (42.5)	84 (57.5)		0.7(0.37 – 1.34)
Middle	148 (45)	57 (38.5)	91 (61.5)	0.831	0.83 (0.44-1.59)
High	51 (13.4)	24 (47.1)	27 (52.9)		
Smoking:					
Non-smoker	208 (69.8)	67 (32.2)	141 (67.8)	<0.001**	
Smoker	137 (30.2)	76 (55.5)	61 (44.5)		2.62(1.68 – 4.09)*
Hypertension:					
Absent	200 (71.8)	55 (27.5)	145 (72.5)	<0.001**	
Present	145 (28.2)	88 (60.7)	57 (39.3)		4.07 (2.58 - 6.42)*
	Mean ± SD	**Mean ± SD**		p∞	
Age (years)	50.09 ± 10.05	48.32 ±11.71		0.134	
Body weight (kg)	82.15 ± 9.44	86.19 ± 13.28		0.002*	
Height (m)	1.66 ± 0.08	1.67 ± 0.08		0.246	
BMI (kg/m^2)	29.97 ±4.31	30.93 ± 4.62		0.049*	
Disease duration (years)	5.94 ±3.92	7.65 ± 3.79		<0.001**	
Fasting blood glucose (mg/dL)	156.9 ± 47.66	203.69 ± 68.99		<0.001**	

**p≤0.001 is statistically highly significant *p<0.05 is statistically significant t COR: crude odds ratio CI Confidence interval #Chi square test ∞independent sample t test

Table (6) Multivariate analysis of risk factors associated with dyslipidemia among the studied (345) patients

Risk factors	β	Odds ratio	95% confidence interval		p
			Lower	Upper	
Body weight	0.023	1.023	0.998	1.049	0.066
Duration	0.084	1.088	1.013	1.169	0.021*
Uncontrolled DM	1.508	4.52	2.443	8.363	<0.001**

Risk factors	β	Odds ratio	95% confidence interval		p
			Lower	Upper	
Hypertension	0.643	1.902	1.445	2.504	<0.001**
Smoking	0.527	1.693	1.282	2.236	<0.001**
Fasting blood glucose	0.006	1.006	1.001	1.012	0.025*

**p≤0.001 is statistically highly significant *p<0.05 is statistically significant DM: diabetes mellitus

Table (7) Relation between dyslipidemia and diabetic foot risk among the studied (345) patients:

Dyslipidemia	IDF diabetic foot risk strata				
	Total N=345 (%)	**Low N=70 (%)**	**Intermediate N=45 (%)**	**High N=81 (%)**	**Very high N=149 (%)**
Present	143 (41.4)	10 (7)	15 (10.5)	41 (28.7)	77 (53.8)
Absent	202 (58.6)	60 (29.7)	30 (14.9)	40 (19.8)	72 (35.6)
COR (95% CI)		**1**	3 (1.2 - 7.47)	6.15 (2.77-13.67)	6.42 (3.05 - 13.48)
p#			0.016*	<0.001**	<0.001**

**p≤0.001 is statistically highly significant *p<0.05 is statistically significant COR: crude odds ratio CI Confidence interval. # Chi square for trend test IDF International diabetic federation

DISCUSSION

Dyslipidemia was prevalent among 41.4% of the patients. Hypertriglyceridemia represents the commonest form followed by increase LDL cholesterol levels.

The prevalence of dyslipidemia among the diabetic patients has varied in different studies, and its frequency is up to 88% of diabetes population [8,10].

Abdelghani et al. [12] reported that about one third of diabetic patients were uncontrolled. They reported that uncontrolled diabetes significantly increased risk of dyslipidemia by 2.81 folds. Dyslipidemia was significantly higher in patients with longer duration (≥10 years).

In a prior research included 94 Egyptian type 2 diabetic patients, 53.2% of their patients had hypertriglyceridemia, 46.9% of them had hypercholesterolemia, 45.9% had abnormal LDL-cholesterol level and 25.5% of them had low HDL level. Fasting blood glucose and glycosylated hemoglobin were significantly higher among patients with dyslipidemia [6].

Another study reported that dyslipidemia was present in 65.6%. Individual lipid abnormality of elevated LDL-cholesterol, total cholesterol, TG, and reduced HDL-cholesterol were identified in 43.8%, 23.7%, 40.6%, and 41.9% of study subjects, respectively. The prevalence of dyslipidemia was significantly associated with hypertension, increasing body mass index, aging, and longer duration of diabetes mellitus [7]

Bekle and colleagues conveyed that only 11.6% of their patients had combined dyslipidemia while hypertriglyceridemia was prevalent in 65.6% [8].

The prevalence of low HDL-cholesterol in that study is almost comparable to the finding from United Arab Emirates [13].

In a case control study enrolled 350 Libyan diabetic patients and 150 age, sex matched healthy control, diabetic patients had a statistically significant higher total cholesterol, TG, LDL-cholesterol and lower HDL cholesterol[14]

In a previous cross-sectional study in Bengladish on 366 patients with T2DM, Low HDL level is the most frequent type of abnormality in 59.3%. Poor glycemic control, prolonged duration, coexisting hypertension predicts dyslipidemia [15]

Another study from Jordan denoted that 77.2%, 83.1%, 83.9%, and 91.5% were the prevalence of total cholesterol, TG, low HDL-cholesterol, and high LDL-cholesterol, respectively [16]. Very high prevalence of dyslipidemia in Arabian countries may be due to sharing eating habits with food is a part of celebrations, poor adherence to healthy life style or ethnic roots. It seems to be a great problem to be solved.

A Chinese study reported that prevalence of dyslipidemia was 34.64%. A study conducted in Ethiopia revealed that there is much higher prevalence of all components of lipid profile yet not low HDL-C [17]

Similarly, hypertriacylglyceridemia was the major lipid parameter disorder in previous studies who reported similar ratios in Hyderabad (60%) and Sudan (48.8%) [18-19]

Hypertriglyceridemia might be attributed to that amplified hepatic secretion of very low density lipoprotein (VLDL) and deferred clearance of TG rich lipoproteins increased levels of substrates for TG production, enhanced mobilization of free fatty acid (FFA) from adipose tissue and increased in the

blood of DM patients as observed in the present study. Elevated TG levels are a common dyslipidemic feature accompanying T2DM and prediabetes states [20]

HDL cholesterol dyslipidemia in T2DM is higher in previous studies in Hyderabad (71%), Nepal (20%), Sudan (93%) and Ghana (26%). The disparity can be attributed to differences in genetics, life style and management techniques [21]

The current result pointed to smoking as a significant risk factor for developing dyslipidemia. Smoking is one of the important risk factors of cardiovascular disease. It is incorporated in developing arteriosclerotic diseases; impairing blood pressure control, lipid and glucose metabolism. Additively, it exacerbates diabetic associated microangiopathy and microangiopathy [22]. Smoking cessation improves lipid metabolism, and potentially glucose metabolism. Also, it may lessen risk of compromised glucose tolerance, developing type 2 diabetes, and diabetic microangiopathy **[23]**.

In agreement with the current study, the prevalence of dyslipidemia was higher for uncontrolled patients [24-25]. HbA1c is a potent marker for dyslipidemia and both the macro- and micro-vascular complications [26]

Lebovitz et al, [27] advocated a lipotoxic mechanism of triglyceride by which it can interfere with gastric or neural pathway which regulates glycemic control. This throws the patient in a vicious circle.

Glycemic control is the most important predictor for diabetic related complications and deaths. In the present study, most patients with dyslipidemia were uncontrolled.

Increasing body weight non-significantly increased risk of dyslipidemia by 1.023 folds among the studied patients. Obese individuals who have dyslipidemia represented only 12.5% in the study by Niyibizi and colleagues [28] where dyslipidemia was prevalent in 20%. In an Iranian study, it was observed that correlation happened between BMI and total cholesterol, LDL cholesterol, TG [29]

According to a previous study, BMI was positively and significantly associated with serum total cholesterol, LDL-C, and TG. Thus, this finding confirmed that BMI still can predict the patients' lipid level in the blood and considered as an alternative method to determine blood lipid levels [30]

A prior cohort study conveyed a significant positive correlation between TC, LDL cholesterol and blood pressure [22,31].The statistically significant relation between presence of hypertension and dyslipidemia. It can be attributed to peripheral resistance which affects BP, leads to narrowing of blood vessels in T2DM patients which eventually increase blood pressure [22]. Duration of diabetes was associated with higher incidence of dyslipidemia of TC, LDL cholesterol in agreement to our study [22].

To our knowledge, it is the first Egyptian study that correlates risk of diabetic foot with dyslipidemia. Using low risk as reference category, dyslipidemia significantly increased risk of intermediate, high and very high risk for diabetic foot by 3, 6.15 and 6.42 folds respectively

Pinto A., et al., [32] showed higher prevalence of dyslipidemia in patients with diabetic foot ulcers. Besides, they also reported a significant positive correlation between dyslipidemia, levels of IL-6 and resistin which are adipocytokines that may contribute to insulin resistance and to the development of inflammatory responses [33]

A higher prevalence of major cardiovascular risk factors such as hypercholesterolemia, LDL plasma levels > 130 mg/dL, hypertriglyceridemia, and microalbuminuria/proteinuria were reported in diabetic foot patients compared with diabetic patients without foot complications and this finding is consistent with the hypothesis that diabetic foot syndrome in diabetic subjects could represent a possible marker of cardiovascular risk [(33)].

Obesity, waist circumference, and dyslipidemia, were statistically significant risk factors for diabetic foot and can be strongly linked with diabetic foot ulcer [34] in disharmony with Mohammed et al. [35].

Being cross-sectional in nature, this study can only suggest but not prove the actual risk factor can predict the dyslipidemia or time lag for each factor to produce that risk. Our sample size was relatively small applied in a single center.

By the end we concluded that dyslipidemia was prevalent in diabetic patients. Hypertriglyceridemia was the commonest form. Increasing duration of diabetes, FBG, uncontrolled diabetes, comorbid hypertension were significant risk factor for dyslipidemia. Dyslipidemia significantly increased diabetic foot risk.

RECOMMENDATION

Good control of diabetes, training physicians on foot care with emphasis on importance of comprehensive patient care and educating them about IDF risk stratification are recommended for early detection of complications hence improving patient outcome

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