Original article

Cardiovascular Risk Stratification for Patients with Diabetes in Tripoli- Libya (2013-2022)

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Abstract

Background and aims. *Diabetes complications have a considerable effect on the quality of life and patient survival, mainly with respect to cardiovascular disease. This study aimed to review the Cardiovascular Disease risk categories for patients with diabetes according to the international guideline, European Societies Cardiology 2019 guidelines* **Methods**. *All patients with diabetes who attended out patient's clinic at the National, Diabetes Center start from Sep 2013 till April 2022 were interviewed and examined, demography data include: their ages, smoking habits, measurement of weight &height for Body Mass Index measure, as well as blood pressure measurement and fasting lipid profile. Assessment for cardiovascular disease risk in every patient by the history of previous cardiovascular events, assessment of diabetes as disease duration, as well as the presence of end end-organ damage then classified according to ESC 2021 into three groups: very high risk, high risk, moderates cardiovascular disease risks, the data was statistical analysis by SPSS.* **Results**. *1024 individuals with diabetes (65% females), mean age 54.11±14.649 years, the duration of diabetes were variable from newly diagnosis in 260 (20.5%), up to more than 10 years in 475(37.5%), body mass index as a measure for weight control were high (≥30%) in 803 patients (78%), smoking habit were active in 126 individuals. Dyslipidemia in 45 cases, blood pressure was uncontrolled even with drugs in 300 cases, end-organ damage as an indication for micro-vascular complication of diabetes was present as retinopathy in 472 patients (46.09%), nephropathy in 539 patients (52.6%), peripheral neuropathy in 645 patients (62.98%), established cardiovascular disease were positive in 289 patients (28.22%), then risk calculation was applied .it shows three groups: very high-risk group were in 645 patients (62.98%), the high-risk group were in 445 patients (43.45%), moderates group were in 66 patients (6.44%) cardiovascular disease risks.* **Conclusions**. *The study showed that nearly two-thirds of our patients with diabetes belong to the very high-risk category of cardiovascular risk. Patients with diabetes required accurate cardiovascular disease risk stratification to direct suitable management for the degree of the risk, and need a more aggressive approach to control modifiable factors such as hypertension, dyslipidemia obesity, and smoking habit.*

Keywords: *Diabetes Mellitus, Body Mass Index, European Societies Cardiology, Tripoli, Libya.*

Introduction

Diabetes Mellitus is well known to be associated with an increased risk of coronary heart disease, ischemic stroke (two to fourfold times compared with nondiabetic patients), and a 1.5 to 3.6-fold increase in mortality [1]. Also, a major risk factor for heart failure, peripheral arterial insufficiency, and microvascular complications, hence will be affecting life quality and expectancy, as patients with diabetes have a reduction in life expectancy of about 4–8 years, compared with individuals without diabetes [2]. Moreover, cardiovascular risk (CVR) factors in diabetic patients are more common compared with nondiabetic as 75–80% of diabetic patients suffer from hypertension, 70–80% present high LDL-cholesterol levels, and 60–70% are clinically obese. incremental CVD risk is not equally distributed among diabetic patients [3], mortality rates after acute events were more than that in nondiabetic patients where the post-infarction mortality rates were 40% greater in comparison with non-diabetic patients [4].

According to WHO data released in 2021, the prevalence of diabetes increased from 108 million in 1980 to 422 million in 2014. And noticed rising more rapidly in low- and middle-income countries than in high-income countries5, Cardiovascular complications account for more than 70% of all hospital admissions in diabetic patients in the USA [6].

In the general population, studies and guidelines were developed for estimating the risk of initial CVD events [7,8], which used The variables of age, gender, total cholesterol (TC), high-density lipoprotein cholesterol (HDL-C), systolic blood pressure (SBP), diabetes mellitus (DM), and current smoking in their assessment of risk factors, with important limitations like ignorance of parameters affecting risks in patients with diabetes such as duration of DM, type 1 diabetes, or T2D [9,10]. By the year 2016 American Diabetes Association Standards of Diabetes Care, recommended the use of a risk factor-based approach to decide on the initiation of statin therapy. It recommends risk stratification including 3 variables: age, the existence of previous cardiovascular events, and the presence or not of risk factors [11], and in n 2019, the European Society of Cardiology (ESC) and the European Association for the Study of Diabetes (EASD) released updated guidelines for the management of diabetes, pre-diabetes, and CV diseases [12]. Our aim of this study is to focus on the most common CVR factors in DM in Libya and grade our patients to facilitate their management according to the new guidelines.

Methodology
All the patients who attended the outpatient clinic at the National Diabetes Center starting from Sep 2013 to March 2022, were included in the study. where demography data include their age, smoking habit, measurement of weight &height for Body Mass Index measures, as well as blood pressure measurement, and fasting lipid profile. Duration of diabetes, with an assessment of diabetes control by HBA1c measures. Assessment for cardiovascular disease risk in every Patient including patients with established Atherosclerotic cardiovascular disease by documented clinical ASCVD concerns previous Acute Myocardial Infarction, Acute Coronary Syndromes Coronary revascularization, and other arterial revascularization procedures, stroke, and TIA aortic aneurysm and Peripheral Arterial Disease Presence of end-organ damage as microvascular complications by dilated pupil fundus eye examination (by an ophthalmologist) for the presence of diabetic retinopathy, and evaluation of Kidney function is reported as an eGFR using estimating equations, the Modification of Diet in Renal Disease (MDRD) study equation, which includes the patient's age, sex, race, and serum creatinine to estimate GFR [1]. Microalbuminuria is defined as an albumin-creatinine ratio (ACR) of 30-300 mg/g from a spot urine collection, 30-300 mg/24 hours in a 24-hour urine collection, or 20-200 mg/min in a timed urine collection. If protein is detected, then conditions like infection, congestive heart failure, pregnancy, severe hypertension, or hematuria must be excluded also due to the wide intra-individual difference of urinary albumin measurement, three tests were performed and found to be positive over a 3- to 6-month period before making a definitive diagnosis of persistent proteinuria [13].
Any patient with e GFR <45 ml/min/1.73m2 irrespective of albuminuria, or eGFR=45-59 ml/min/1.73m2 and microalbuminuria(ACR>300mg/g) or presence of microvascular disease in atleast3 different sites (microalbuminuria plus retinopathy plus neuropathy) is considered to have Diabetes Kidney Disease after exclusion of other causes of Chronic Kidney Disease such as hypertensive kidney disease.

Feet examination by 10g monofilament foot examination to assess peripheral neuropathy. Then classified according to ESC 2021 into
As a very high risk, high risk, moderates risk groups.
Cardiovascular risk categories in patients with diabetes (T2DM and Patients with T1DM above40 years of age may also be classified according to these criteria
A- Very High-risk Patients with DM and established ASCVD, and /or severe Target Organ Damage, GFR <45 ml/min/1.73m2 irrespective of albuminuria, eGFR45-59 ml/min/1.73m2 and microalbuminuria(ACR>300mg/g) and presence of microvascular disease in atleast3 different sites (microalbuminuria plus retinopathy plus neuropathy)
B-High Risk Patients with DM without ASCVD and /or severe Target Organ Damage, and not fulfilling the moderate risk criteria
C-Moderate Risk Patients with well-controlled short–standing DM (< 10 years), no evidence of Target Organ Damage, and no additional ASCVD risk factors
Major Risk Factors for ASCVD are (Age, hypertension, dyslipidemia, smoking, and obesity.

Statistical analysis
They were interviewed and examined by means of standardized methods, the data was Statistical analysis by SPP, for continuous variables are expressed as mean ± standard deviation and analyzed using descriptive statistics, Cross tabulation, Chi-square tests to calculate Pearson Chi-square, Asymp.Sig (2-sided) as p-value 95% confidence intervals (95% CI) with < 0.05 was considered statistically significant. All calculations were performed with Statistical v10.0 (StatSoft, Tulsa, OK, USA) or STATA v11 (StataCorp LLC, College Station, Texas, USA).

To assess the Cardio-vascular Disease risks for patients with diabetes according to the international guideline, ESC 2021 guidelines, and to monitor whether these risk factors are controlled in patients with established ASCVD in the routine practice of preventive measures applied.

Results
A total of 1265 patients were enrolled in this study, only 1024 patients completed the study their mean age of 54.11±14.649 years (females represent 65% of the studied sample, there were different duration of diabetes between the studied sample, varying from newly 260 patients (20.5%), from two to five years, were 138 patients (10.9%), from five to ten years were 152 patients (12%), and above ten years' diabetes duration were 475 patients (37.5%). active smoking in 126(12.3%),
The body weight of studied patients ranged from 44 kg to a maximum of 186 kg (85.67 ±1.73), Body Mass Index was calculated for each patient where underweight were present (1.66 %), normal BMI (19.44%), overweight was in (24.55%), and obesity was in (25.44%), with patients with morbid obesity were in (28.88), so 803(78%) were uncontrolled body weight. uncontrolled blood pressure even with treatment present in 300 (29%), uncontrolled dyslipidemia present in 45(4.39%), uncontrolled hyperglycemi9(78%), and presence of one or more diabetes microvascular complications (diabetes retinopathy, diabetes Kidney Disease, Peripheral diabetes neuropathy) was present in 645 (62.9%).
End-organ damage as an indication for micro-vascular complications of diabetes was present as retinopathy in 472 patients (46.09%), nephropathy in 539(52.6%) patients, peripheral neuropathy in 645 patients (62.98%), the presence of end-organ damage (at least one micro-vascular complication) indicate very high-risk group patients were present in 645(62.98%)
The establish cardiovascular disease was positive in 289 patients (28.22%), then risk calculation was applied .it showed three groups: very high-risk group in 645 patients (62.98%), high-risk group in 445 patients (43.45%), moderates group were in66 patients (6.44%).

Table1: Distribution of the patient character according to diabetes duration (clinical presentation: history, examination) at National Diabetes Center (Tripoli-Libya 2013-2020).

Characters	Newly diagnosed	2-5 years duration	5-10 years duration	>10 years duration	Total	Asymp.sig (2-sided)
1-Sex: Female	162	93	98	318	671 (65%	Chi Square
Male	98	46	54	157	355(35%)	tests 0.615
Total	260	139	152	475		
2-Age ≤32	17	13	8	6	44	
33-53	137	58	65	107	367	Chi Square
54-74	98	57	67	297	519	tests
75≥	8	11	12	65	96	0.000
Total	260	139	152	475		
3-Smoking						
Non	169	101	106	352	728	Linear by
Ex-smoker	27	13	13	43	96	linear association
Passive	21	8	11	35	75	0.005
Active	43	17	22	44	126	
Total	260	139	152	474	1025	
4-Body Mass Index	7	0	2	8	17	
Underweight	46	32	27	93	198	
Normal	63	31	44	112	250	
Overweight	95	37	28	135	259	0.20
Obese	83	38	49	124	294	
Morbid obese	258	138	150	472	1018	

						Chi Squ test
5-Blood Pressure Normal						
Controlled with treatment	108	61	40	103	312	Linear by
	87	47	63	211	408	linear association test
Uncontrolled	65	30	48	161	300	
Total	260	138	151	475	1024	0.005
H/o CVD						
Yes	43	25	35	186	289	0.000
No	217	113	116	289	735	
Total	260	138	151	475	1024	

Table 2: Distribution of the patient's character according to diabetes duration (investigations) at National Diabetes Center (Tripoli-Libya 2013-2020)

Characters	Newly diagnosed	2-5 years duration	5-10 years duration	>10 years duration	Total	Asymp.sig (2-sided)
1-HBA1c=<6g%	53	9	6	13	81	
6.5-7	50	30	23	42	145	
8-9	85	74	83	198	440	0.000
>10	72	25	40	222	358	
Total	260	138	152	475	1025	
2-Fasting lipid profile						
Normal	58	34	17	28	137	
Controlled with treatment	189	101	128	424	842	0.000
Uncontrolled	13	3	6	23	45	
Total	260	138	151	475	1024	

Table3: Distribution of the patient's character according to diabetes duration &presence of micro-vascular complications at National Diabetes Center (Tripoli-Libya 2013-2020)

Characters	Newly diagnosed	2-5 years duration	5-10 years duration	>10 years duration	Total	Asymp.sig (2-sided)
Presence of diabetes Retinopathy	32	36	75	328	472	
No	228	102	76	147	552	0.000
Total	260	138	151	475	1024	
Presence of diabetes Kidney disease	211	91	78	159	539	
No	49	47	73	316	485	0.000
Total	260	138	151	475	1024	
Presence of diabetic peripheral neuropathy	85	64	95	401	645	
No	175	74	56	74	379	0.000
Total	260	138	151	475	1024	

Table 4: Distribution of the patient's character in very high-risk CVD risk group at National Diabetes Center (Tripoli-Libya 2013-2020).

Character	Very high risk	P value
Sex:	Yes	
Female	420	0.942
Male	225	
2-Age ≤32	13	
33-53	180	
54-74	373	0.000
75≥	79	
3-Smoking		
Non	467	
Ex-smoker	58	0.633
Passive	42	
Active	77	
4-Body Mass Index		
Underweight	11	
Normal	116	
Overweight	149	0.08
Obese	171	
Morbid obese	195	
5-Duration		
Newly	85	
2-5 years	64	0.000
5-10 years	95	
>10 years	401	
5-Blood Pressure Normal	131	
Controlled with treatment	300	0.000
Uncontrolled	214	
HBA1c		
Controlled with treatment	14	0.000
Uncontrolled	631	
Fasting lipid profile Normal	40	
Controlled with treatment	568	0.000
Uncontrolled	37	

Discussion

This study was done in the main hospital in Tripoli specializing in the follow-up, assessment, and treatment of diabetes and its complication (The national diabetic center), hyperglycemia treatment alone is effective to prevent and delaying microvascular complications, but not for CVD [14], in fact, Reducing CVD achieved by optimal management of all risk factors. The randomized controlled trials showed that careful treatment of hyperglycemia, multifactorial management of risk factors, and new treatment agents, such as SGLT2 inhibitors and GLP1-RA, had significantly improved the cardiovascular outcomes [15].

According to the ESC guidelines 2021 on cardiovascular disease prevention, CVD risk patients in diabetes are divided into 3 groups very high, high, and moderate risk categories [16]. Our result showed a high percentage of our patients with diabetes are in a very risk category (62.98%), while (43.45%) are in the high-risk category, and (6.44%) of the patients are in the moderate's risk category. Thus higher percentage in the high and moderate risk groups compared with that in China which showed (65.6%), (7.5%), and (0.6%) of patients

were included in "very high risk," "high risk," and "moderate risk" categories [17], and more than observed in Spain where they found 53.4% of their patients with diabetes were in a very high-risk group, 39.6% in the high-risk group, and 7% in moderate-risk group [18]. As compared with an Indian study [19] where (60.5%) of their patients with diabetes were classified as Very high risk, (39.5%) were classified as High risk, we had a similar percentage of the very high-risk category, but a higher percentage of the high–risk category

Conclusions

Nearly two-thirds of our patients with diabetes belong to the very high-risk category of the cardiovascular risk. A further extension of nationwide cardiovascular risk identification programs and prevention strategies among patients with diabetes are required to reduce the occurrence of cardiovascular diseases, and more aggressive approach is needed to control modifiable factors such as hypertension, dyslipidemia obesity, and smoking habit.

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