КАРДИОМЕТАБОЛИЧЕСКИЕ ФАКТОРЫ РИСКА И ОСОБЕННОСТИ ЭЛЕКТРОКАРДИОГРАММЫ У ПАЦИЕНТОВ С НЕИНФИЦИРОВАННЫМИ ЯЗВЕННЫМИ ДЕФЕКТАМИ СТОПЫ И БЕЗ НИХ ПРИ САХАРНОМ ДИАБЕТЕ 2 ТИПА: СРАВНИТЕЛЬНОЕ ИССЛЕДОВАНИЕ

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ОБОСНОВАНИЕ. Многочисленные исследования показали, что сахарный диабет 2 типа (СД2) вызывает изменение параметров электрокардиограммы независимо от наличия патологии микрососудистого или макрососудистого русла.
ЦЕЛЬ. Продемонстрировать различия в параметрах электрокардиограмм между пациентами с СД2 с неинфицированными диабетическими язвами стопы и пациентами с СД2 без язв.
МАТЕРИАЛЫ И МЕТОДЫ. Исследование проводилось в клинической больнице Шар в провинции Сулеймания в Ираке с июля 2018 г. по июнь 2019 г. 167 участников были распределены в три группы: в группу I (СД2, n=72), в группу II (СД2 с неинфицированными диабетическими язвами стопы, n=65) и в группу III (здоровые лица, n=30). Пациентам измеряли артериальное давление, регистрировали электрокардиограмму и оценивали антропометрические показатели. Гликемический и липидный профили в сыворотке крови натощак оценивались в рамках лабораторных тестов.
РЕЗУЛЬТАТЫ. У пациентов II группы по сравнению с пациентами I группы зарегистрированы значимо более низкое диастолическое артериальное давление, более высокий индекс пульсового давления и более высокий уровень глюкозы в сыворотке крови натощак. У больных I группы отмечались значимо более высокая частота сердечных сокращений, укорочение интервала TQ и расширение дисперсии QRS. У пациентов II группы интервал TQ был значимо короче, чем у пациентов I группы (523,6±136,4 мс против 579,2±110,0 мс соответственно).
ЗАКЛЮЧЕНИЕ. При неинфицированных язвах стоп интервал TQ, показатель нарушения реполяризации желудочков, намного короче и связан с высоким пульсовым давлением. Таким образом, изменения электрокардиограммы являются результатом сердечно-сосудистой вегетативной дисфункции.

КЛЮЧЕВЫЕ СЛОВА: сахарный диабет 2 типа; синдром диабетической стопы; электрокардиография; кардиометаболические факторы риска; укорочение интервала TQ; индекс пульсового давления

CARDIOMETABOLIC RISK FACTORS AND ELECTROCARDIOGRAM RESULTS IN TYPE 2 DIABETES PATIENTS WITH OR WITHOUT NON-INFECTED FOOT ULCERS: A COMPARATIVE STUDY

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BACKGROUND: Numerous investigations have demonstrated that type-2 diabetes (T2D) causes electrocardiographic alterations, whether or not there are microvascular or macrovascular problems.
AIM: With respect to glycemic control and the accompanying cardio-metabolic risk factors, the goal of this study was to demonstrate the variations in electrocardiogram records between T2D patients with non-infected diabetic foot ulcers (DFUs) and those without ulcers.
METHODS: This study was performed in the Shar Teaching Hospital in the Sulaimani Governorate-Iraq from July 2018 to June 2019. 167 participants were grouped into Group I (T2D, n=72); Group II (T2D with non-infected diabetic foot ulcers, n=65) and Group III (healthy subjects, n= 30). Blood pressure, electrocardiography, and anthropometric measurements were taken. Fasting serum glucose and lipid profiles were assessed as part of laboratory tests.
RESULTS: Group II patients significantly differed from Group I by having lower diastolic blood pressure, a higher pulse pressure index, and a higher fasting serum glucose. The Group I patients had a significantly higher heart rate, a shortening of TQ-interval and widening of QRS dispersion. Group II patients had a significantly shorter TQ-interval compared with the corresponding value of Group I patients (523.6±136.4ms versus 579.2±110.0ms, respectively). These changes in the electrocardiograms are not related to the cardiometabolic risk factors.

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CONCLUSION: In the non-infected diabetic foot, the TQ-interval, a measure of ventricular repolarization impairment, is much shorter and is linked to a broad pulse pressure. According to this finding, the electrocardiographic abnormalities are a result of cardiovascular autonomic dysfunction.

KEYWORDS: Type 2 diabetes mellitus; Diabetic foot ulcers; Electrocardiograph; Cardiometabolic risk factors; Shortening TQ-interval, Pulse pressure index

BACKGROUND

Type 2 diabetes (T2D) is a major risk factor for cardiovascular events and has been linked to some cardio-metabolic risk factors such as obesity, hypertension, and dyslipidemia [1]. Cardiac complications of diabetes include cardiomyopathy, ischemic heart diseases, left ventricular dysfunction, heart failure, and arrhythmias [2, 3]. In the presence or absence of microvascular or macrovascular problems, several studies revealed that T2D causes electrocardiogram abnormalities. Heart rate variability, a longer Tp-Te slope of the T-wave, a longer QTcB interval, and a longer ventricular repolarization were all observed on the electrocardiogram [4–6]. Some of these ECG abnormalities are associated with diabetic complications, including diabetic retinopathy, nephropathy, autonomic neuropathy, ketoacidosis, and poor diabetic control [7, 8]. Diabetic foot ulcers (DFUs) are one of the T2D complications that carry higher rates of morbidity and mortality. A triad of etiological factors are involved in the cause of DFUs, including neuropathy, vascular dysfunction, and immunological impairment in poorly controlled diabetic patients. Lavery et al. described the diabetic foot syndrome (DFS) as a combination of diabetic sensory neuropathy, limited joint mobility, immunopathy, peripheral arterial disease, foot ulceration, and Charcot arthropathy [9]. Previous studies found that prolongation of the QTc interval in DFUs patients carried a higher rate of mortality [10, 11]. Moreover, those patients showed a significant QTc dispersion, which attributed to the dysfunction of the autonomic nervous system [12]. The rationale for this study is that DFUs is a disease of different pathological conditions in which the cardiac complications may be different from those diabetic patients without DFUs.

RESEARCH AIM

This study aimed to show the differences in the electrocardiograph records between T2D patients presented with non-infected DFUs and those without ulcers, taking into consideration the glycemic control, and the associated cardio-metabolic risk factors.

MATERIALS AND METHODS

Ethical approval and consent form to participate

The Institutional Scientific Committee at the University of Sulaimani approved this cross-sectional study, according to the guidelines of Helsinki. Any test that is done to the patient should not be harmful, and the patient is free to withdraw from the study. A consent form was obtained from each patient prior to admission to the study.

Setting

The study was conducted in the Department of Pharmacology, College of Medicine at the University of Sulaimani in cooperation with the Shar Teaching Hospital in the Sulaimani governorate-Iraq from July 1st 2021 to March 31st 2022.

Study Design

This is an observational cross-sectional study. The patients were recruited from the outpatients' departments of Shar and the Center of Diabetes in Sulaimani, Iraq. The eligible patients were both sex adults.

The criteria of inclusion were known as T2D patients, irrespective of the duration of disease. The diagnosis of DFS was confirmed by the consultants in endocrinology using the Wagner-Meggitt classification of DFS. According to the Wagner-Meggitt classification, the DFS classifies lesions into six grades (0–5). In this study, patients with grades 0, 1, and 2 of the Wagner classification were included. The criteria of exclusion are Type-1 diabetes, clinical evidence of complications of diabetes (including retinopathy, nephropathy, and current cardiovascular events), cardiac arrhythmias, smoking, pregnancy and lactating and nursing mothers, chronic liver and kidney diseases, clinical and laboratory evidence of electrolyte disturbances, and current history of medications (e.g., macrolides; antipsychotics, antidepressants; antihistamines, antiarrhythmias. Consultants of endocrinology and the authors examined each patient thoroughly.

Clinical Assessment

The authors examined and interviewed each patient, taking characteristics of the patients that related to the objective of the study. Anthropometric measurements, including body weight (kg), height (m), and waist circumference (cm), were determined. Body weight (kg) divided by squared height (m) was equal to the body mass index (kg/m^2). The waist (cm) to height (cm) ratio was calculated, and any value that is ≥ 0.5 indicates the patient is at risk of cardiovascular events. Blood pressure (mmHg) was measured by a manual mercury sphygmomanometer at a sitting position after 3 minutes of rest. The mean of the three readings was considered in this study. Pulse pressure is equal to the systolic *minus* diastolic blood pressure. Mean arterial pressure is equal to diastolic blood pressure *plus* 1/3 of the pulse pressure. The pulse pressure index as an indicator of arterial stiffness was determined as pulse pressure divided by systolic blood pressure.

Fasting serum glucose (mg/dl), lipid profile (including triglyceride, total cholesterol, and high density lipoprotein-cholesterol (HDL-c), and glycosylated hemoglobin (HbA1c%) were determined as routine investigations in the Center of Diabetes laboratories. HDL-c level was determined by subtracting the serum HDL-c from the serum total cholesterol.

Then each participant is asked to do the electrocardiogram (ECG) investigation.

The ECG records of sinus rhythm are included in the study. Then the ECG record strips were scanned, and the scanned

picture was magnified by the PC Windows photo viewer to zoom. Each ECG record was examined by two independent cardiologists, blinded to patient information. The following data was obtained:

QRS wave duration (ms); QRS dispersion (ms); heart rate (beats per minute); QTc interval (ms); TQ interval (ms); JT corrected (JTc) interval (ms); QT-index and JT-index.

QTc interval (s): It is calculated by using Bazett's formula:

QTcB = QTm / $\sqrt{RR}$. The corrected (JTc) was calculated by subtracting the duration of the QRS complex from QTcB. QT-index (%) was calculated by using the following formula:

QT-Index (%) = (QT/656) × (heart rate +100).

The JT index is equal to JT-(measured) (heart rate + 100)/518, with a cutoff value of 112 indicating prolonged ventricular repolarization and a ventricular conduction defect. TQ interval represents the duration of the ventricular diastole.

A total number of 72 patients without DFS (Group I), 65 patients with DFS (Group II) and 30 healthy subjects (Group III) were enrolled in the study.

Data analysis

The results are expressed as a number, percentage, and mean ± SD. The difference between the means of the studied groups was analyzed using a two-tailed independent two-sample t-test and a one-way ANOVA (Analysis of Variances) with *post hoc Bonferroni* test. A *p*-value of ≤ 0.05 is the cutoff level of significance. For data analyses, the Statistical Package for the Social Sciences software (SPSS) version 21 (IBM-Compatible Corporation; Chicago, USA) was used.

RESULTS

The data in Table 1 shows that the proportion of females to males, the means ± SDs of the age, and the duration of diabetes in Group II are significantly higher than the corresponding values in Group I. There are no significant differences in the family history of diabetes or history of cardiovascular-related diseases.

Table 2 shows that the anthropometric measurements, including waist circumference, waist-to-height ratio, and

Table 1. Characteristic of the participants

Determinants	Group I (n=72)	Group II (n=65)	P value
Gender (Female : Male)	37:35	47:18	0.012
Age (years)	53.4±9.0	56.7±7.8	0.024
Duration of diabetes (years)	7.8±4.3	10.3±5.6	0.004
Family history of diabetes mellitus (No.)	43 (59.7)	43 (66.2)	0.437
Cardiovascular-related diseases			
Hypertension	33 (45.8)	34 (52.3)	0.449
Dyslipidemia	52 (72.2)	47 (72.3)	0.991
Angina pectoris	3 (4.2)	5 (7.7)	0.376
Myocardial infarction	1 (1.4)	4 (6.2)	0.138

Note: The results are expressed as a number (%) and a mean ± SD. Non-diabetic foot syndrome (Group I); diabetic foot syndrome (Group II). For independent two-sample data, the P value was calculated using the two-tailed t-test, and for categorized data, the Chi-squared test.

Table 2. Assessment of cardio-metabolic risk factors

Determinants	Group I (n= 72)	Group II (n=65)	P value
Waist circumference (cm)	99.5±9.2	101.7±12.6	0.242
Waist-to-height ratio	0.613±0.063	631±0.061	0.092
Body mass index (kg/m^2)	28.9±4.9	29.7±5.7	0.379
Systolic blood pressure (mmHg)	130.4±20.3	132.0±21.5	0.655
Diastolic blood pressure (mmHg)	81.0±9.6	77.0±10.3	**0.020**
Pulse pressure (mmHg)	49.4±14.9	55.0±16.5	**0.039**
Mean arterial blood pressure (mmHg	97.4±12.2	95.3±12.9	0.329
Pulse pressure index	0.373±0.030	0.410±0.071	**<0.001**
Fasting serum glucose (mg/dl)	197.1±69.5	226.9±82.4	**0.023**
Glycated hemoglobin (%)	9.31±1.98	9.6±1.9	0.384
Fasting serum lipid profile			
Cholesterol (mg/dl)	175.9±56.5	176.2±52.4	0.974
Triglyceride (mg/dl)	155.5±82.2	179.1±109.8	0.154
High density lipoprotein-cholesterol (mg/dl)	41.2±11.1	42.8±13.8	0.454
Non-low density lipoprotein-cholesterol (mg/dl)	135.9±59.1	133.4±51.4	0.793
Lipid indices			
Cholesterol index >1	16	17	0.591
Triglyceride index >1	32	28	0.872

Note: The results are expressed as a mean ± SD. Group I is assigned to non-diabetic foot syndrome, and Group II is given to diabetic foot syndrome. A two-tailed t-test for independent two-sample student data and a Chi-squared test for categorized data were used to determine a P-value. Because the level exceeded 400 mg/dl, three cases (from Group I) and one case (from Group II) were excluded from the calculation of the mean value of triglyceride. The lipid indices were calculated using cutoff values of 200 and 160 mg/dl for triglycerides and cholesterol, respectively.

Table 3. Comparison between electrocardiogram of patients with non-diabetic foot and diabetic foot patients referred to the healthy subjects

Electrocardiogram determinants	Group I (n=72)	Group II (n=65)	Group III (n=30)	One way ANOVA		*Posthoc Bonferroni* test (p-value)		
				F-value	p-value			
Heart rate (beat/min)	81.1±10.9	83.4±13.2	72.6±10.6	8.694	**<0.001**	***0.004**	†**<0.001**	0.743
QTcB (ms)	421.1±37.7	429.5±38.9	411.1±33.5	2.547	0.081	0.607	0.082	0.640
TQ (ms)	579.2±110.0	523.6±136.4	694.3±150.1	18.044	**<0.001**	***<0.001**	†**<0.001**	‡**0.038**
QRS duration (ms)	67.6±17.6	68.9±21.4	62.4±11.4	1.319	0.270	0.580	0.334	1.000
QRS dispersion (ms)	22.0±11.5	18.6±9.0	16.8±6.1	4.520	**0.012**	***0.025**	1.000	0.073
QT index	99.4±8.7	100.9±8.9	98.3±14.0	1.039	0.356	1.000	0.527	0.966
JTc (ms)	353.9±41.9	360.6±30.1	348.7±60.8	1.067	0.347	1.000	0.508	0.953
JT index	102.3±12.2	103.3±11.3	100.6±17.8	0.218	0.805	1.000	1.000	1.000

Note: The results are expressed as the mean ± SD. * A comparison between Group III (healthy subjects) and Group I (non-diabetic foot); † A comparison of Group III (healthy subjects) and Group II (diabetic foot); comparison of NDF and DF; ‡ A comparison between Group I (non-diabetic foot) and Group II (diabetic foot). One-way ANOVA was used to calculate the F-value, and the *posthoc Bonferroni* test was used to determine the p-value for the mean difference between independent two-samples.

body mass index, do not significantly differ between Groups I and II. Resting blood pressure measurements of the patients show the mean diastolic blood pressure of Group II patients is significantly lower than the corresponding value of Group I, and this is reflected in the significant difference in the pulse pressure and pulse pressure index (Table 2). The pulse pressure index, as a measurement of arterial stiffness, is significantly increased by 9.9%. Biochemical analysis of lipid variables shows non-significant differences between Group I and Group II, whereas the mean value of fasting serum glucose is significantly increased by 15.1% in Group II compared with Group I (Table 2). A non-significant higher mean value of glycosylated hemoglobin was observed in Group II compared with Group I.

Table 3 shows the assessment of ECG records of the participants enrolled in this study. Group I patients have a significantly higher resting heart rate, a shorter TQ interval, and a higher QRS dispersion than Group III patients by 8.5 beats/min, 115.1 ms, and 5.2 ms, respectively. Patients with non-infected diabetic foot ulcers (Group II) have a significantly higher resting heart rate and a shorter duration of the TQ interval than the corresponding values of Group III by 10.8 beats/min and 170.7ms, respectively. The duration of the TQ interval of Group II patients is significantly less than the corresponding value of Group I (523.6±136.4 versus 523.6±136.4, p=0.038 (Table 3).

DISCUSSION

The results of this study show that patients with non-infected DFUs have significant abnormal electrocardiogram and hemodynamic changes compared with patients without DFUs. In general, complications of diabetes (as in this study, the DFUs) are usually observed in patients with long-standing diabetes and uncontrolled or poorly controlled diabetes, as this study documented [13]. Our results showed that the proportion of females to males with DFUs is higher than the corresponding proportion of patients without DFUs. This observation is in agreement with other studies [14]. The proportions of patients with a previous or current history of cardiovascular-related diseases non-significantly differ between Groups I and II. Therefore, the possibility of bias in the assessment of the ECG records is eliminated. Our study documented the previous studies that demonstrated non-significant associations between hypertension and dyslipidemia with DFUs [14]. Except for fasting serum glucose and lower diastolic blood pressure, the cardiometabolic risk factors are not significantly different between Groups I and II. Dyslipidemia as a cardiometabolic risk factor has been demonstrated in diabetics with or without DFUs. Previous studies showed that dyslipidemia is an independent risk factor for the severe DFUs that necessitate amputation [15]. The mean value of the BMI of the Group II patients is a non-significantly higher than that of the Group I. Therefore, BMI is not a predictor or associated cardiometabolic risk factor in DFUs, but it may be of clinical importance in the prognosis of DFUs as other studies demonstrate that the delay of ulcer healing is associated with a higher BMI [16]. Autonomic neuropathy is a part of the polyneuropathy complication of diabetes and peripheral sensory neuropathy is one of the etiological factors of DFUs [17]. Therefore, the significant low diastolic blood pressure observed in this study could be related to the autonomic neuropathy. The risk of lower diastolic blood pressure that was observed in this study is reflected in the high pulse pressure-index, which is a marker of arterial stiffness, and it may be involved in the ECG records changes in Group II [18]. The changes in the ECGs records that reported in this study are similar to those reported by [19]. Therefore, our study adds another piece of information that the ECG records of DFUs patients have a higher heart rate and a shortening of the TQ period. The clinical significance of the shortening TQ period is related to the impairment of ventricular repolarization and predisposing cardiac arrhythmias. Acute cardiac events were reported in diabetic patients with severe foot infections and were commonly associated with tachycardia [20]. Wang et al. reported a prolonged QT-interval as in our study and suggested that a prolonged QTc interval is a predictor of cardiac death [10]. The possible explanation of the shortening of the TQ period and low pulse pressure is the presence of cardiovascular autonomic neuropathy or dysfunction. The strength of this study was related to the well matching of many cardiometabolic risk factors between Group I and II, and the patients were

presented with non-infected ulcers, which indicates the bias of inflammation was eliminated. The limitations of the study included the patients recruited from a single center, and ambulatory ECG records (24 hour Holter monitoring) were not carried due to the shortage of financial support.

CONCLUSION

We conclude that the shortening of the TQ-period, which indicates ventricular repolarization impairment, differs significantly from that seen in patients without DFUs. The relationship between TQ period shortening and wide pulse pressure is related to cardiovascular autonomic dysfunction or neuropathy, which may coexist with DFUs.

OTHER INFORMATION

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All the authors approved the final version of the article before the publication and expressed their consent to be responsible for all aspects of the work, which implies proper investigation and resolving of issues related to the accuracy or integrity of any part of the work.

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