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ORIGINAL RESEARCH

Study Of Association Between QTC (Corrected QT) Interval And Microalbuminuria In Patients Of Type – 2 Diabetes Mellitus

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ABSTRACT

Background: One of the most significant complications of type 2 diabetes mellitus (T2DM) is diabetic nephropathy, the leading cause of end-stage renal disease. Another important clinical marker in patients with type 2 diabetes is QTc interval prolongation. We aimed to study the association between QTc interval prolongation and microalbuminuria in patients with T2DM.

Objective: The primary objective of this study was to examine the association between QTc interval prolongation and microalbuminuria in patients with T2DM. The secondary objective was to correlate the prolongation of the QTc interval with the duration of T2DM.

Materials and methods: This study was conducted as a single-centre, case control study. Patients aged more than 18 with T2DM with and without microalbuminuria were recruited into the study and control groups, and various parameters, including QTC intervals, were recorded.

Results: A total of 100 patients were enrolled in the study, with 50 patients with microalbuminuria forming the study group and 50 patients without microalbuminuria forming the control group. There was a statistically significant association between microalbuminuria with a prolonged QTc interval, a longer duration of T2DM, higher haemoglobinAIc (HbA1c) levels, and higher serum creatinine values.

INTRODUCTION

Diabetes Mellitus (DM) refers to a group of metabolic disorders that share the common phenotype of hyperglycemia. According to International Diabetes Federation (IDF) 10th edition, it is reported that around 537 million adults are currently affected by diabetes globally, which is roughly 1 in 10 individuals. The number is anticipated to rise to roughly 700 million by 2045. India has seen an explosive rise in the diabetes epidemic in the recent decades. In fact, India currently has the second-highest prevalence of Diabetes in the world. According to IDF data, the prevalence of diabetes among individuals aged 20-79 years in India is 9.6%, which translates to nearly 74,194,600 cases, with almost 50% of them going undiagnosed. The total cases are expected to rise to approximately 100 million by 2030.[3]

Diabetic nephropathy (DN) is a common complication of DM and is characterized by persistent albuminuria (>300 mg/day or >200 μg/min) in 2 out of 3 tests within 3 to 6 months, a gradual decline in glomerular filtration rate (GFR) and hypertension. Microalbuminuria is defined as 30-300 mg of urinary albumin in a 24-hour urine collection or 30-300 microg/mg creatinine in a spot collection. Albuminuria is considered as a significant predictor of cardiovascular morbidity & mortality, even without cardiovascular risk factors. The urinary albumin creatinine ratio (UACR) is a recently developed method proven to have excellent sensitivity & specificity. This is because urinary creatinine excretion remains relatively constant, allowing for the

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correction of changes in urinary volume that affect the urinary albumin concentration by expressing the albumin excretion as a ratio of concentration of albumin to that of creatinine. The UACR also has the advantage of offering immediate results, enabling rapid monitoring of treatment.

Among all the complications of diabetes, autonomic neuropathy is least understood and acknowledged, even though it affects both survival and quality of life negatively. Although clinical symptoms present long after the onset of Diabetes, subclinical dysfunction occurs within 1 year of the diagnosis of Type 2 DM and 2 years of Type 1 DM. [19] Cardiovascular autonomic neuropathy (CAN) impacts the autonomic nerve fibers supplying heart & blood vessels, resulting in a disturbance in sympathetic innervation & potential electrical instability leading to dangerous ventricular arrhythmias. It significantly affects the daily life of patients & can lead to life-threatening consequences.[23] CAN is determined by a lack of autonomic control over the cardiovascular system, with the presence of diabetes, after ruling out other potential causes. Various cardiovascular autonomic tests are used to diagnose this condition. Heart rate variability during deep breathing is the most widely used test; its specificity is

80.[27] The main clinical presentations of CAN are resting heart rate > 100 beats per minute & orthostatic hypotension.

Patients diagnosed with diabetes mellitus have 2-10 times increased risk of sudden cardiac death. The electrocardiogram (ECG) is a simple, noninvasive diagnostic tool to detect functional & structural abnormality of heart with cardiac electrical activity. The QT interval reflects electrical depolarization and repolarization of both right & left ventricles. [38] The duration of QT interval is influenced by heart rate i.e. a faster heart rate results in a shorter QT interval. Bazett's Formula is utilized to adjust the QT interval based on the heart rate, calculating the heart rate-corrected QT interval

(QTc). The QTc typically falls within the range of 0.35 to 0.43 seconds.[39]

$$QTc = \frac{QT}{\sqrt{RR}}$$

Following the latest ESC guidelines, the risk of premature death from a cardiovascular cause in patients with T2DM and microalbuminuria is about 4 times that of patients with normoalbuminuria. [47,48] Stratifying patients of diabetes helps to predict future cardiovascular events, silent myocardial ischemia, & subclinical CAD. Furthermore, personalized care and reduced morbidity & mortality rates necessitate risk assessment.[49] Early pharmacological interventions are shown to provide significant cardiovascular and end-organ protection.

MATERIALS AND METHODS

This study was conducted in 100 individuals with Type-2 Diabetes mellitus presenting in the Department of Medicine (both indoor & outdoor) of Guru Nanak Dev Hospital, Amritsar after seeking permission from Institutional Ethics Committee, Government Medical College, Amritsar. Written informed consent was taken from all those who fulfill the inclusion criteria and were willing to participate in the study. This study aimed to investigate the association between microalbuminuria & QTc in patients with type-2 diabetes mellitus. 100 type -2 Diabetes mellitus patients of both genders with age between 35-95 years were included in the study- 50 having nephropathy were considered as cases and the other 50 serving as controls without nephropathy. Type -2 Diabetes mellitus patients of both genders with age between 35-95 years were included in the study.

Known hypertensive patients with mean blood pressure ≥ 140/90 mm of Hg or patients already on antihypertensive medication , patients with uncomplicated or complicated urinary tract infection , patients with systemic disorders such as chronic liver disease, blood disorders, or autoimmune disorders, patients on Anti-inflammatory drugs, systemic or topical steroids ,patients having diseases affecting urinary protein excretion such as nephrotic syndrome, renal artery stenosis, or dehydration state, patients of ischemic heart disease , cerebrovascular accident , organophosphorus poisoning, psychiatric drug overdosage, & antiarrhythmic medications which are known to cause QT prolongation,pregnant females were excluded from the study.

Data were collected as per the protocol through history taking, including name, age, sex, history of diabetes, treatment history, and drug history, as well as through a general physical examination with height, weight, BMI, pulse rate, and blood pressure, and systemic examination was done. An electrocardiograph was taken on the day of admission; the most prolonged QT interval was measured manually. It was measured from the start of the QRS complex to the end of the downslope of the T wave (crossing the isoelectric line) in the lead II. The RR interval was calculated by manually counting the number of small boxes between the two peaks of the R wave in lead II.QT and RR intervals were measured manually. Corrected QT interval (QT c) by Bazett 1920 et al.

Type 2 diabetes mellitus as per criteria laid by the American Diabetes Association, any one of the below criteria: Fasting blood glucose ≥126 mg/dL, postprandial blood sugar ≥200 mg/dL, HbA1c ≥6.5 gm%, and random blood sugar ≥200mg/dL with osmotic symptoms (polyuria, polydipsia, weight loss).Nephropathy was diagnosed with the help of urine albumin creatinine ratio. Creatinine level <30 mg/g creatinine was considered normal, and creatinine level 30-300 mg/g creatinine was considered microalbuminuria. Creatinine level >300 mg/g was considered proteinuria. Typically, the QTc value is ≤0.44 seconds. It is prolonged if > 0.45 sec.

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STATISTICAL ANALYSIS

The data was collected systematically & comparison of demographic and laboratory characteristics were done between both the groups and appropriate significance tests were applied including Student's t test, Mann Whitney Test & Chi-square test. Analysis was done using Microsoft excel 2010 & SPSS 21.0 statistical package (SPSS, Chicago, IL). Data was presented as Mean± Standard Deviation (SD). p value of <0.05 was considered significant.

RESULTS

The present study was conducted in the Department of Medicine, Guru Nanak Dev Hospital attached to Government Medical College, Amritsar to study the association between QTc and Microalbuminuria.

This was a Case-Control study done on 100 diabetic subjects- 50 of which were included in "Group A" and were without nephropathy & 50 with nephropathy included in "Group B" serving as cases who presented to the Medicine department (indoor/ outdoor) of Guru Nanak Dev Hospital and fulfilled the inclusion criteria of the study.

The age of all patients included in study varied b/w 35-95 years. In Group A, most of the patients (56%) were in age group of 51-65 years followed by 24% in 35-50 years, 20% in 66-80years & none in 81-95years. In Group B, most of the patients (62%) were in age group of 51-65 years followed by 16% in 35-50 years, 18% in 66-80 years & 4% in 81-95 years. The average age in Group A was 57.78 ± 11.84 years& average age in Group B was 59.22 ±9.95 years. This difference in mean age b/w both the groups was statistically insignificant as p-value was 0.390. In Group A, 46% of the patients were males & 54% were females whereas in Group B, 52% patients were males & 48% were females. This difference was statistically insignificant as p-value was 0.548.

The average BMI for groups A & B was 24.62 ± 4.16 kg/m2 and 28.28 ± 3.45 kg/m2, respectively. The average BMI of group A was lower than that of Group B, & the p value of 0.001 indicated that this difference in the distribution of BMI was statistically significant.

The mean duration of diabetes in Group A was 5.21 ± 2.76 years; while in Group B was 11.9 ± 6.24 years. The mean duration of diabetes in Group B was significantly higher as compared to Group A with the p-value being 0.001.

COMPARISON OF DURATION OF DIABETES BETWEEN BOTH GROUPS

Diabetes duration (years)	Group A		Group B	
	Number of subjects	%	Number of subjects	%
1-5 years	31	62.00	11	22.00
5-10 years	12	24.00	19	38.00
>10 years	7	14.00	20	40.00
Total	50	100.00	50	100.00
Mean duration	5.21 ± 2.76		11.96 ± 6.24	
p-value	0.001			

The mean serum creatinine in Group A was 1.22 ± 1.44 mg/dl while in Group B was 2.2 ± 2.33 mg/dl. The mean creatinine in Group B was significantly higher as compared to Group A as the p-value was 0.011.

The mean HbA1c Group A was 7.9 ± 2.2 % while in Group B was 9.4 ± 2.4 %. Mean HbA1c was higher in group B and this difference was substantially significant as the p-value was 0.003.

The mean fasting blood sugar in group A was 130.22 ± 20.14 mg/dL & in group B was 162.74 ± 24.05 mg/dL. The association between FBS and microalbuminuria was found to be statistically significant as the p-value was 0.001.

Mean microalbuminuria in Group A was 10.41 ± 5.16mg/g, while in Group B was 110.23 ± 9.4 mg/g. The mean microalbuminuria in Group B was higher as compared to Group A & this difference was substantially significant (p = 0.001).

The corrected QT interval was normal in most (98%) of the patients of T2DM without nephropathy. Prevalence of prolonged QTc was higher in group B as compared to group A, which was 66 % in patients of T2DM with nephropathy. The mean QTc was 378.20 ± 24.07ms in group A & 447.98 ± 45.02ms in group B. The p-value is 0.001 which is highly significant.

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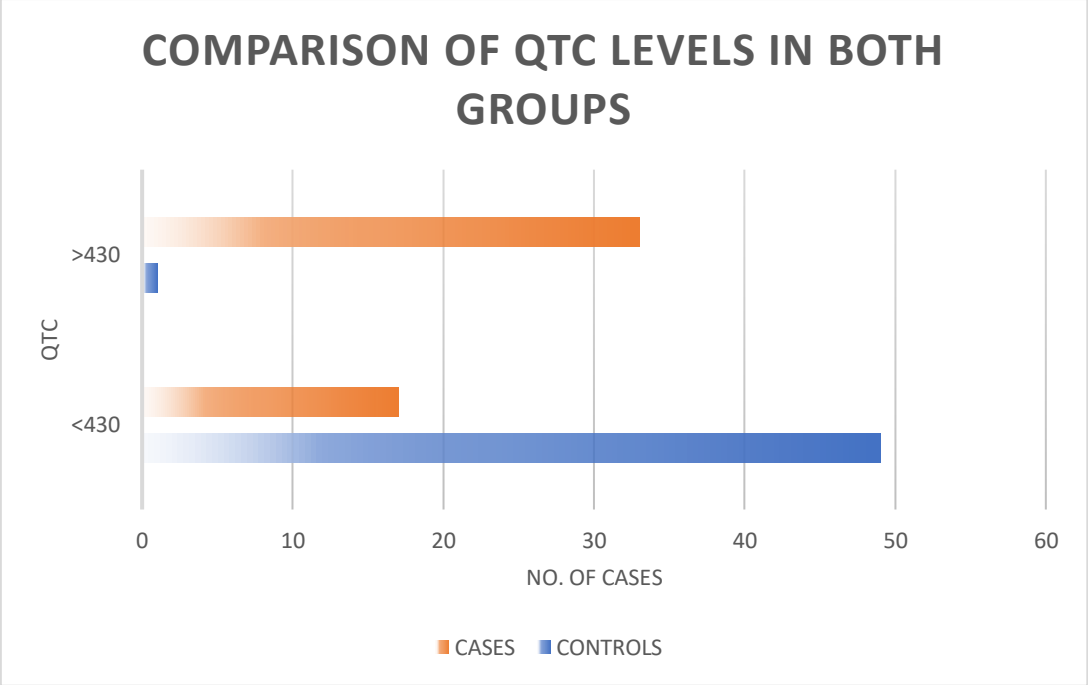

The mean QTc (ms) in the age group 35-50 years was 432.28 ± 29.04, in age 50- 65 was 436.30 ± 52.27,in 65-80 was 431.43 ± 28.87,& in 80-95 was 467.20 ± 34.22 ms. The p-value was 0.78, therefore no significant association was seen between age & QTc among cases. Among cases, the mean QTc in males was 437.49 ± 26.08 ms& in females was 432.47 ± 57.18 ms. No significant association was seen between gender & QTc as the p-value was 0.686. Subjects with QTc within the reference range had an average BMI of 26.6±3.3 kg/m2, while subjects with prolonged QTc had an average BMI of 28.6± 3.5 kg/m2. A noteworthy correlation b/w BMI & QTc was demonstrated, with a p-value of 0.005. The mean duration of diabetes in subjects with QTc interval within reference range was 10.1 ± 3.5years & in subjects with prolonged QTc interval was 12.8 ± 4.83 years. A significant correlation was observed between QTc & duration of diabetes with p-value being 0.002. The mean HbA1c in subjects with QTc within normal limits was 9.048 ± 2.57% & in subjects with prolonged QTc was 10.10 ± 2.26%. Although HbA1c was higher in subjects with prolonged QTc, this association was not statistically significant with the p-value being 0.16.

SHOWING RELATIONSHIP BETWEEN QTc AND HbA1c

QTc(ms)	Hba1C(%)	
	Mean	SD
<430	9.048	2.5705
>430	10.100	2.2622
p-value (Mann Whitney Test)	0.161	

The mean cholesterol in subjects with QTc within normal limits was 190.94 ± 50.25 mg/dL & in subjects with prolonged QTc was 164.48 ± 54.36 mg/dL. The p-value was 0.419. Therefore, no significant correlation was observed between cholesterol & QTc.

The mean microalbuminuria in patients with QTc within normal range was 94.3 ± 30.22 mg/g & in patients with prolonged QTc was 118.4 ± 44.86 mg/g. The mean Microalbuminuria& QTc showed positive relationship in group B. QTc was significantly increased in patients of T2DM with nephropathy. The p value is 0.002.

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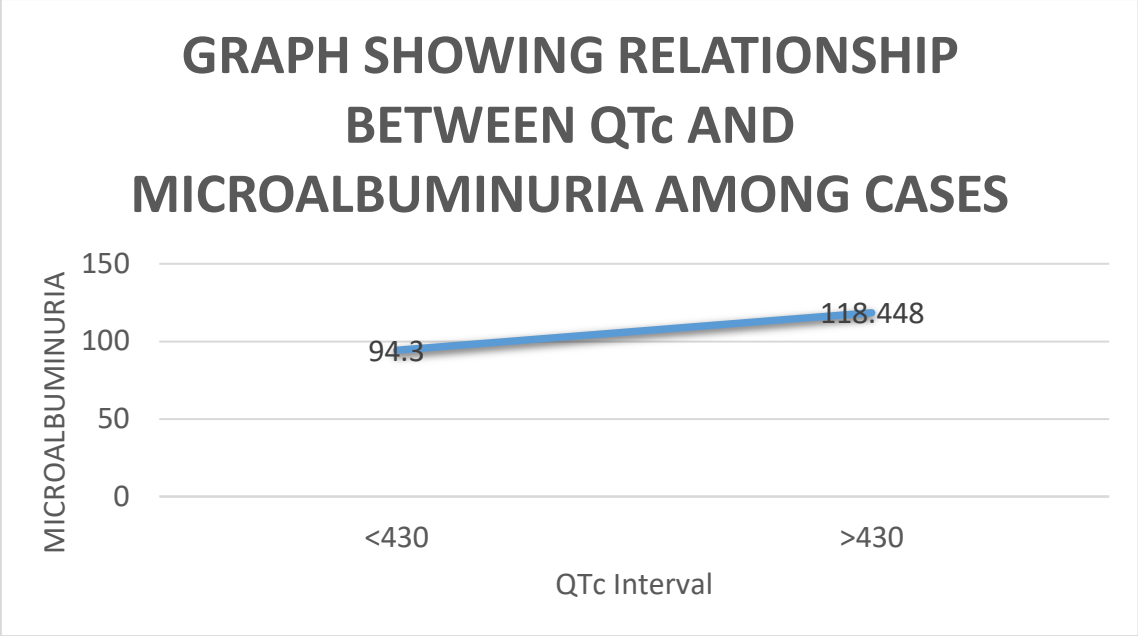

DISCUSSION

India is the diabetic capital of the world. Diabetes has long been considered as a cardiovascular risk equivalent. Microalbuminuria is an early marker of kidney disease in diabetic patients. According to ESC guidelines, in patients who have diabetes mellitus, microalbuminuria is an independent marker for cardiovascular disease. Cardiac autonomic neuropathy is a frequent and life-threatening consequence of Type-2 diabetes. QTc can be used as a marker of CAN. Failing to detect CAN in its early stages can lead to increased morbidity & mortality. This study aimed to investigate the association between microalbuminuria & QTc in patients with type-2 diabetes mellitus. The study included 100 diabetic patients-50 having nephropathy were considered as cases and the other 50 serving as controls without nephropathy.

The patients included in this study were in age from 35 to 95 years. The age group of 51-65 years was most frequent in both groups, accounting for 62% of cases & 56% of controls. The patients in Group A had a mean age of 57.78±11.84 years & in Group B had 59.22±9.95 years. The difference in age distribution was not statistically significant between the two groups (p-value 0.390).

Similarly, in Manasa dixit[73] et al study, most of the patients were in 5-7th decade of life. In Dominic[74] et al study, it was seen that average age in the cases was 59.9±12.2 years and in the controls was 56.2±9.6 years. No significant association was identified between age & microalbuminuria.

In the current study, 26 males and 24 females had microalbuminuria constituting 52% and 48% of cases respectively, & 23 males and 27 females were without microalbuminuria constituting 46% and 54% of controls respectively. There was no significant association observed between gender & microalbuminuria (p=0.315). 43Likewise, S. Dominic's study observed no significant link between gender & microalbuminuria (p-value = 0.5).

The average duration of diabetes was 11.96±6.24 years in cases, & in the controls, it was 5.21±2.76 years. Within the cases, 22% (11 individuals), 38% (19 individuals), & 40% (20 individuals) had diabetes for < 5 years, 6-10 years, & more than 10 years, respectively. A statistically significant connection was found between duration of diabetes & microalbuminuria (p=0.001).

The findings were similar to study conducted by Sawarthia[71] et al wherein 57.9% of cases had a diabetes duration of 5-10 years, and a substantially significant link was identified between the duration of diabetes & microalbuminuria(p-value 0.004). Likewise, in a study by Dominic[74] et al, the median duration of diabetes was 10 years-11.5 years in cases and 8 years in control group. A statistically significant association was established b/w microalbuminuria & duration of diabetes (p=0.034). In the present study, the BMI of 38% of the cases and 24% of the controls was within the range of 25-29.9kg/m2. The average BMI for the case group was 24.62 ± 4.16 kg/m2, while for the control group, it was 28.28 ± 3.45kg/m2. A statistically significant association was identified b/w BMI & Microalbuminuria (p=0.001). The findings were comparable to a study by Sawarthia[71] et al- the majority (36 cases) had a BMI in the range of 24-29.99 kg/m2, 2 cases had BMI less than 18.5, 33 cases had BMI in the range of 18.5-23.9 and 24 cases had BMI more than 30kg/m2.They also revealed a statistically significant connection between BMI distribution & microalbuminuria (p=0.07).Rutter[54] et al also observed a significant relationship between BMI and micro-albuminuria(p-value<0.01).

In the current study, it was seen that 70% of diabetics with micro-albuminuria had FBS of 126 mg/dl or

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higher, while 30% had FBS below 126 mg/dl. A statistically significant association was observed in increased FBS values between diabetic patients with & without microalbuminuria (p-value 0.001). The findings of our study are in concordance with Sawarthia[71] et al's study, where 66.3% of diabetics with 44microalbuminuria had a FBS of 126 mg/dl or higher, with 33.7% having FBS below 126 mg/dl. There was a significant contrast in raised fasting blood glucose levels between diabetic patients with and without microalbuminuria (p-value 0.038). In present study, 88% of cases and 76% of controls had an Hba1c level of 6.5 or higher. The average Hba1c level in the cases group was 9.40±2.49%, while in control group, it was 7.93±2.24%. A statistically significant correlation was observed between Hba1c levels & microalbuminuria (p=0.003). Similar to our results, in a study by Xiang li[60] et al, mean HbA1c in cases was 8.1±2.1% and in controls was 7.6±1.8%.

A statistically significant correlation was observed b/w Hba1c levels & microalbuminuria (p<0.01). Likewise, in a study by S.Dominic[74] et al, the average HbA1c level in the study group was 9±1.9%, while in the control group, it was 7.8±1.6% & this association was statistically significant (p<0.001).

Majority of diabetic individuals with microalbuminuria (56%) exhibited serum creatinine levels below 1.7 mg/dl. However, 44% of the patients had serum creatinine levels equal to or greater than 1.7 mg/dl. A significant rise in serum creatinine levels was observed between diabetic patients with & without microalbuminuria (p-value 0.011).These findings are comparable to a study by Dominic[74] et al, where the average creatinine level in the normo-albuminuria group was 0.9±0.3mg/g, while in the microalbuminuria group, it was 1.1±0.4mg/g, with a statistically significant variance (p-value 0.011).

The present study revealed that 68% of all diabetic participants had cardiac autonomic neuropathy. In a study by Pappachan[59] et al in South India on 100 diabetic patients, the prevalence of CAN was 60%.

The mean corrected QT interval was measured in different age groups among cases in the current study. The mean QT interval(ms) for individuals aged 35-50years was 432.28±29.04, for those aged 51-65 it was 436.30±52.27, for the 66-80 age group it was 431.43±28.87, & for individuals aged 81-95, it was 45467.20±34.22. No significant association was observed between age & mean QTc in cases (p-value 0.783).Similarly, no significant connection was seen between the mean corrected QT interval & age in the Sawarthia[71] et al study (p-value 0.985). Among the cases in the current study, average corrected QT interval for males was 437.49±26.08ms, while for females it was 432.47±57.18ms (p-value 0.686). No statistically significant correlation was observed b/w gender and QTc in the cases. Likewise, in a study by Aburisheh[70] et al, QTc was prolonged in 102 cases- 44 of which were males & 57 were females. There was no discernible difference in gender allocation of the study subjects. The prevalence of QTc prolongation did not exhibit significant differences based on gender (p-value = 0.135).

The current study found that the average BMI for subjects with a mean QTc of less than 430ms was 26.65±3.31kg/m2, while patients with prolonged QTc had an average BMI of 28.61±3.53 kg/m2 (p-value 0.005). A significant association was observed between BMI & QTc. Kobayashi[64] et al study also revealed a notable connection between BMI and QTc (p value 0.03). BMI is a well-established risk factor for cardiovascular diseases & is also linked to a less favorable prognosis for diabetes.

The average duration of diabetes in patients with prolonged QTc was 12.87±4.83years, while it was 10.17±3.56years in those with QTc within reference range. We found a significant link between QTc and duration of DM (p-value=0.002). Previous study by Manasa Dixit C[73] et al also demonstrated that longer duration of DM increases the possibility of cardiac autonomic neuropathy. In another study by Jennifer[67] et al, 38.40% (48 persons), 29.6% (37 persons), 14.4% (18 persons), 13.60% (17 persons), & 4% (5 persons) had diabetes for < 5 years, 6-10 years, 11- 15 years, 16-20 years, & more than 20 years, respectively. It was observed that duration of DM is significantly associated with cardiac autonomic neuropathy.

In the present study, subjects with a mean QTc of less than 430ms had a mean HbA1c of 9.04±2.57%, while subjects with prolonged QTc had a mean HbA1c of 4610.10±2.26% (p-value 0.161). No significant association was found between HbA1c and QTc. Aburisheh[70] et al study also found no significant association b/w prolonged QTc & HbA1c (p-value 0.565). Both studies did not find a significant correlation b/w HbA1c & CAN, indicating that poor short-term glycemic control does not correlate with the prevalence of CAN. This could be because a single measurement of HbA1c in T2DM does not accurately reflect the pattern of glycemic control over the previous years, which is responsible for chronic diabetic complications such as neuropathy, retinopathy, & nephropathy.

The average cholesterol level in individuals with a mean QTc of less than 430ms was 190±50.25mg/dL, while in those with prolonged QTc was 164.48±54.36mg/dL (p-value 0.419). No significant correlation between cholesterol & QTc was observed in this study. Similarly in a study by Kobayashiet al, it was seen that there was no significant link between cholesterol and QTc (p-value 0.57).

In our study, prolonged QTc was observed in 33 (66%) out of 50 patients diagnosed with microalbuminuria, while only 1 (2%) out of 50 patients without microalbuminuria showed QTc prolongation. The average QTc for the cases group was 447.98±45.02ms, whereas for the control group, it was 378.20±24.07ms. We observed a substantially significant variance between QTc &

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microalbuminuria (p=0.001). Similarly, S Dominicet al found that 58.3% of patients with microalbuminuria had prolonged QTc, whereas only 16.7% of those without microalbuminuria had prolonged QTc. The correlation b/w prolonged QTc & microalbuminuria was also found to be statistically significant (p<0.001). Additionally, Kumar SSSet al in 2021 established a significant association between cardiac autonomic neuropathy (QTc prolongation) & microalbuminuria in their study.

From the above discussion, it can be concluded that prevalence of prolonged QTc in diabetic patients is considerably high. The prolongation of QTc interval is significantly associated with nephropathy as compared to diabetic patients without nephropathy.

This study had several limitations: Patients from only one hospital were involved in this study which can cause a limit to this study. In the current study, we measured only the QTc interval & not the other QT parameters, like QT dispersion.

SUMMARY AND CONCLUSIONS

The present study has shown that the prevalence of prolonged QTc interval is higher in patients of type-2 diabetes mellitus with nephropathy as compared to those without nephropathy. Duration of diabetes is also significantly associated with CAN as shown in our study. These findings have both epidemiological &clinical relevance so as to explain increased cardiovascular mortality in type 2 DM with and without nephropathy.

QTc serves as a marker for increased cardiovascular morbidity & mortality in type 2 diabetes. Therefore, all diabetic patients having microalbuminuria should be screened with ECG to look for QTc interval prolongation. ECG is easily available, cost effective and routinely done. Early screening and diagnosis along with 52 education of patients and intensive glycemic control helps to arrest the progression of CAN in the diabetic population.

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