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Pattern of Electrocardiographic Abnormalities among Patients on long-term psychotropic Medication in a Nigerian Tertiary Hospital

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ABSTRACT:
Background: Psychotropic medications are administered for various psychiatric conditions with associated significant high morbidity and mortality. Electrocardiographic (ECG) abnormalities had been reported among patients on psychotropic medications; however, baseline or follow-up ECGs are rarely done during routine clinical practice especially in developing country. **Objective**: To study the pattern of ECG abnormalities among patient using psychotropic drugs in a Nigerian tertiary hospital. **Materials and Methods**: This was a cross-sectional comparative study conducted in a population of 134 psychiatric patients on psychotropics and 75 controls. All subjects had detailed clinical history and resting electrocardiogram done. ECG abnormalities were divided into minor and major abnormalities based on Novacode criteria. A 95% confidence interval was used while statistical significance was set at $P < 0.05$. Results: The prevalence of at least one ECG abnormality in the patient was 35.8% and comparable with the control group of 28.0% (p=0.249). Overall, 32.8% and 3.0% of the patients as well as 25.3% and 2.7% of the controls had minor and major ECG abnormalities respectively based on Novacode Criteria and these differences were not statistically different. The male patients had a considerably higher prevalence of ECG abnormality than their female counterparts (P<0.001). **Conclusion**: Psychotropic drugs result in abnormal ECG changes in therapeutic doses howbeit mostly benign. This study provides some evidence that there is a need for regular ECG monitoring especially in patients with other cardiovascular risk factors.

Keywords: Psychotropic drugs, ECG abnormalities, Nigerian Hospital

INTRODUCTION:

Psychotropic medications are regarded as drugs that can impact the mind, emotions, and behavior. Psychotropic drugs are broadly categorized into antipsychotics, antidepressants, anxiolytics, mood stabilizers, and stimulants (1). Patients with psychiatric disorders have been reported by several studies to have high rates of cardiovascular morbidity and mortality (2, 3). Adverse cardiovascular effects of psychiatric drugs have been shown to be a significant contribution to the high morbidity and mortality whether or not patients have a history of cardiac disease (4, 5). Electrocardiographic (ECG) abnormalities had been reported to be quite common among patients on psychotropic medications (5, 6). Sinus tachycardia, sinus bradycardia, supraventricular tachycardia, atrial fibrillation, atrioventricular nodal delay, widening QRS complex, premature atrial contraction, premature ventricular contraction, and prolonged QTc are among the ECG abnormalities linked to psychiatric medications. Moosa *et al* reported of 67.5% patients on psychotropics had ECG abnormalities (5).

In Nigeria and the majority of African nations, the burden of cardiovascular disease and

electrocardiographic changes among these patient groups is grossly underreported. Patients taking psychiatric medications in developing countries like Nigeria rarely undergo baseline or follow-up ECGs before and throughout medication use. There are also few studies conducted in Africa that evaluate the ECG changes in patients on psychotropic medication (6) necessitating further research into the cardiac adverse effects experienced by these drug users.

MATERIALS AND METHODS:

Study design and settings:

This was a hospital-based cross-sectional comparative descriptive study. between December 2018 and June 2019 at the Psychiatric clinic of the Ekiti State University Teaching Hosipital (EKSUTH), Ado Ekiti, Ekiti State. Ado Ekiti is the capital of Ekiti State in the South Western geopolitical zone of Nigeria.

A total of 209 participants were recruited. This included 134 patients who had been on psychotropic medications for at least 6 months and 75 age and sex-matched healthy individuals as controls. Pertinent history including symptom complex, family and social history pre-morbid personality, and drug history were obtained from the patients as well as important examination findings. Their Psychiatric diagnosis was based on World Health Organization criteria (ICD 10) (7). All the subjects were recruited if they gave informed consent, were at least 18 years old, did not suffer from stroke, liver disease, or renal disease, and were not using non-psychotropic medications known to prolong QTc. Exclusion criteria for the study included any patients or controls with systemic hypertension, diabetes mellitus, known history of heart failure based on a history of symptoms and indications of heart failure in the past or at the time of examination using the Framingham criteria, pregnancy, and hypokalaemia. Every participant was laying supine in a noise-free setting while a resting 12-lead ECG (Zoncare ZQ 1203G) was recorded at a paper speed of 25 mm/sec and vertical calibrations of 1 mV=10 mm. Standardization of leads and specification was done according to the recommendations of the American Heart Association/American College of Cardiology (AHA/ACC) (8-11). The ECG parameters determined include heart rate, rhythm, cardiac axis, amplitude and duration of the P wave, PR intervals, QRS duration, QRS amplitude, ST segment, T wave, and observed mean QT. Left ventricular hypertrophy (LVH) was determined using methods previously validated in black Africans of Nigerian extraction (12) as well as Sokolow-Lyon criteria (13). Observed QT (QT_o) was measured from the beginning of the QRS complex to the visual return of the T-wave to the iso-electric line using lead II and the preceding R-R interval was also determined. QTc was calculated by applying Bazett's formula $QTc = QTo/\sqrt{R\text{-}R}$ (14). At least three consecutive cycles were measured and then averaged. ECG abnormalities were divided into minor and major abnormalities based on Novacode criteria (15).

Using IBM SPSS statistics version 25 computer software package, continuous variables were summarized into means and standard deviations (SD) when normally distributed and as the median and interquartile range (IQR) when non-normally distributed. Categorical variables such as patterns of ECG abnormalities were summarized as proportions. The overall prevalence of ECG abnormalities was calculated as the proportion of patients with at least one abnormal ECG finding. Bivariate analysis was done with the use of Chi-square and Fisher's exact test for categorical variables as appropriate while student t-test was used to compare means of continuous variables. A 95% confidence interval (CI) was used while statistical significance was set at $P < 0.05$.

The Ethics and Research Committee of Ekiti State University Teaching Hospital, Ado-Ekiti, Ekiti State, Nigeria, approved the study protocol. The ethical clearance protocol number is EKSUTH A67/2018/11/009. The recruitment process included all consecutively presenting adult patients who were 18 years of age or older, of both gender, and who matched the aforementioned inclusion criteria. All of the chosen patients signed an informed consent form. Patients received assurances that their information would be kept private. There was nothing in the questionnaire that could be utilized to identify the patients.

RESULTS:

A total number of 209 subjects completed the study. These included 134 subjects on psychotropic medications and 75 healthy control subjects well matched for age and gender distribution. There was no statistical difference in the mean age of the patients (35.2±11.1 years) and that of the controls (32.7±10.9 years) (p=0.09). The patient's group consisted of 63 males (47%) and 71 females (53%) while the control group consisted of 41 males (54.7%) and 34 females (45.3%) (p =0.29). The details are summarized in Table 1. Table 2 showed the characteristics of psychotropic drugs used by patients either singly or in combination. Eighty-five (63.40%) of the patients had schizophrenia, 36 (26.90%) depression, 8 (5.97%) bipolar disorder, 4 (3%) substance-related disorders, and 1 (0.67%) somatoform disorder.

Table 1: Demographic and clinical characteristics of both study groups

Characteristics	**Patients (134)** **N (%)**	**Control (75)** **N (%)**	**Significance**
Gender			
Male	63 (47.0)	41 (54.7)	χ^2=1.126
Female	71 (53.0)	34 (45.3)	P=0.289
Smoking	3 (2.2)	0 (0)	¥P=0.218
Alcohol	4 (3.0)	2 (2.7)	¥P=1.000
Characteristics	**Patients (134)** **Mean ± SD**	**Control (75)** **Mean ± SD**	**P-value**
Age (years)	35.2±11.1	32.7±10.9	0.09
Weight (Kg)	68.9±10.2	68.1±8.1	0.545
BMI (Kg/m^2)	25.2±3.4	24.7±2.8	0.239

Key: χ^2 - Chi square, ¥= Fisher's exact test, BMI- body mass index.

Table 2: Distribution of psychiatry diagnoses among patients

Psychiatry diagnoses	**Frequency**
Schizophrenia	85 (63.40%)
Depression	36 (26.90%)
Bipolar	8 (5.97%)
Substance related disorder	4 (3.00%)
Somatoform disorder	1 (0.67%)

The psychotropic medications received by patients included antipsychotics (risperidone, chlorpromazine, haloperidol, trifluoperazine, fluphenazine (depot), flupentixol (depot), olanzapine), antidepressants (amitriptyline, fluoxetine, escitalopram), and mood stabilizers (valproate and carbamazepine). Patients were receiving antipsychotics alone, antidepressants alone, or a combination of antipsychotic and/or antidepressant and/or mood stabilizers. The characteristics of psychotropic drugs used by patients either singly or in combination are shown in Table 3.

Table 3: Characteristics of Psychotropic drugs used by patients either singly or in combination (n=134)

Psychotropic drugs	**Frequency** **N (%)**
Antipsychotics	
Risperidone	86 (64.20%)
Chlorpromazine	18 (13.40%)
Trifluoperazine	13 (9.70%)
Fluphenazine (oral)	1 (0.75%)
Haloperidol	8 (5.97%)
Olanzapine	10 (7.46%)
Clozapine	6 (4.48%)
Fluphenazine (depot),	4 (3.0%)
Depixol	1 (0.75%)
Antidepressants	
Amitriptylline	19 (14.2%)
Fluoxetine	12 (8.96%)
Escitalopram	1 (0.75%)
Mood stabilzers	
Carbamazepine	12 (8.96%)
Valproate	1 (0.75%)

Table 4 showed the distribution of ECG abnormalities based on the psychotropic drugs group. ECG abnormalities occurred most frequently in patients on antipsychotics in combination with mood stabilizers (46.7%) and least frequently in patients on antidepressants alone (12.5%). Furthermore, the ECG abnormalities recorded among the patients included cardiac arrhythmias (22.7%), prolonged PR interval (4.5%), chamber enlargement (11.2%), abnormal T wave (11.2%), and intraventricular conduction defect (3.7%). The commonest cardiac arrhythmia was sinus tachycardia (10.7%). None of the patients had high-grade ventricular arrhythmias or atrial fibrillation.

Table 4: Distribution of ECG abnormalities based on psychotropic drugs group

Psychotropic drug groups	Prevalence of ECG abnormalities N (%)
Antipsychotic alone (91)	34 (37.4)

Antidepressant alone (8)	1 (12.5)
Antipsychotic + Antidepressant (17)	5 (29.4)
Antipsychotic + mood stabilizers (15)	7(46.7)
Antipsychotic + Antidepressant + mood stabilizers (3)	1 (33.3)

Comparing the prevalence of various ECG abnormalities across both study groups, the prevalence of at least one ECG abnormality in the patient was 35.8% and not statistically significantly higher than and control groups of 28.0% (p=0.249). The prevalence of left ventricular hypertrophy, arrhythmias, left atrial enlargement, atrioventricular conduction block, intraventricular conduction defect, abnormal ST segment, and T wave abnormalities were not statistically significantly different in both study groups. However, the mean QTc in the patient group (415.24 ±28.4ms) was statistically significantly higher than the mean QTc (390.4±21.9 ms) of the control group (p-value <0.001). In addition, among the observed arrhythmias, the prevalence of sinus tachycardia 14 (10.7%) in the patient group was statistically significantly higher than the control 0 (0%) (p=0.006) unlike other types of arrhythmias which were statistically insignificant. All the above findings are summarised in Table 5.

Table 5: ECG characteristics of study population

	Patients (134)		**Controls (75)**		
	N	**%**	**N**	**%**	
Abnormal ECG findings	48	35.8	21	28	$\chi^2 = 1.330$ p =0.249
Arrhythmias	31	23.1	12	16.0	$\chi^2 = 1.498$ p= 0.221
Sinus tachycardia	14	10.7	0	0	¥p = 0.004*
Sinus bradycardia	12	9.0	11	14.7	$\chi^2 = 1.602$ p =0.206
PAC	3	2.2	0	0	¥p =0.554
PVC	2	1.5	1	1.3	¥p=1.000
Atrial flutter	0	0	0	0	NC**
Atrial fibrillation	0	0	0	0	NC**
Junctional rhythm	0	0	0	0	NC**
Chamber enlargement	15	11.2	7	9.3	$\chi^2 = 0.177$ p=0.674
Left atrial enlargement	4	3.0	0	0	¥p =0.299
LVH	11	8.2	7	9.3	$\chi^2 = 0.077$ p =0.781
Right atrial enlargement	0	0	0	0	NC**
RVH	0	0	0	0	NC**
Atrioventricular (AV) block	6	4.5	3	4	¥p = 1.000
First degree AV block	6	4.5	3	4	¥p = 1.000
Second degree AV block	0	0	0	0	NC**

Third degree AV block	0	0	0	0	NC**
Intraventricular blocks (IVCD)	5	3.7	6	8	$\chi^2 = 1.757$ p = 0.185
LBBB	0	0	0	0	NC**
RBBB	0	0	0	0	NC**
LAFB	2	1.5	0	0	¥p = 0.537
LPFB	0	0	0	0	NC**
Bifascicular block	0	0	0	0	NC**
Non-specific IVCD	3	2.2	5	8	¥p = 0.139
Repolarization changes	13	8.7	3	4	¥p = 0.139
Abnormal ST segment (elevation or depression)	0	0	0	0	NC**
Abnormal T waves	15	11.2	4	5.3	¥p = 0.212
Pathological Q waves	0	0	0	0	NC**
Characteristics	**Patients (134) Mean ± SD**		**Control (75) Mean ± SD**	**P-value**	
Mean QTc	415.4±28.4		390.4±21.9	P<0.001*	

Key: LAFB- Left anterior fascicular block, LBBB- Left bundle branch block, LPFB- Left posterior fascicular block, LVH- Left ventricular hypertrophy, NC** = Chi square statistics not computed as both cases and controls have the same proportions, PAC- Premature atrial contraction, PVC- Premature ventricular contraction, RBBB- Right bundle branch block, , RVH- Right ventricular hypertrophy, *- significant, ¥= Fisher's exact test, χ^2= chi square.

Overall among the study subjects, 32.8% and 3.0% of the patients as well as 25.3% and 2.7% of the controls had minor and major ECG abnormalities respectively based on Novacode Criteria. These differences in both study groups were not statistically different. This is summarized in Table 6.

Table 6. Pattern of ECG abnormalities in study population based on Novacode Criteria

ECG findings	**Patients (134)**		**Controls (75)**		**Statistical indices**
	N	**%**	**N**	**%**	
Normal	86	64.2	54	72.0	$\chi^2 = 1.330$ P = 0.248
Minor abnormalities	44	32.8	19	25.3	$\chi^2 = 1.285$ P = 0.257
Major abnormalities	4	3.0	2	2.7	¥P = 1.000

Key: χ^2 = Chi square, ¥= Fisher's exact test

The gender differences in the clinical and electrocardiographic parameters of patients on psychotropic drugs are shown in Table 7**.** The prevalence of ECG abnormalities was significantly (P<0.036) higher in males than in females. Likewise, the prevalence of sinus bradycardia, premature atrial tachycardia, left ventricular hypertrophy (LVH), and intraventricular conduction defect were significantly higher in males. In contrast, the mean QTc (427.2 ± 28.7ms) was also significantly higher in the female patients.

Table 7: Gender differences in the ECG characteristics among patients on psychotropic drugs

Variables	**Male(62) Mean ± SD**		**Female(72) Mean ± SD**		**Statistical indices**
QTc (ms)	408.8±24.3		427.2±28.7		p<0.001*
	Male (62)		**Female(72)**		
	N	%	N	%	
Abnormal ECG findings	28	45.2	20	27.8	χ^2 = 4.379 p = 0.036*
Any Arrhythmias	21	33.9	10	13.9	χ^2 = 7.480 p = 0.006*
Sinus tachycardia	5	8.1	9	12.5	χ^2 = 0.701 p = 0.403
Sinus bradycardia	12	19.4	0	0	¥p = <0.001*
Premature atrial contraction	3	4.8	0	0	¥p = 0.10
Premature ventricular contraction	2	3.2	0	0	¥p = 0.212
Atrial flutter	0	0	0	0	NC**
Atrial fibrillation	0	0	0	0	NC**
Junctional rhythm	0	0	0	0	NC**
Chamber enlargement	10	14.5	5	6.9	χ^2 = 2.827 p = 0.093
Left atrial enlargement	1	1.61	3	5.1	¥p = 0.624
Left ventricular hypertrophy	8	12.9	3	3.8	¥p = 0.112
Right atrial enlargement	0	0	0	0	NC**
Right ventricular hypertrophy	0	0	0	0	NC**
Atrioventricular(AV) block	5	8.1	1	1.3	¥p = 0.095
First degree AV block	5	8.1	1	1.3	¥p = 0.095
2nd degree AV block	0	0	0	0	NC**
3rd degree AV block	0	0	0	0	NC**
Intraventricular blocks	5	8.1	0	0	¥p = 0.019*
Left bundle branch block	0	0	0	0	NC**
Right bundle branch block	0	0	0	0	NC**
Left anterior fascicular block	2	3.2	0	0	¥p = 0.212
Left posterior fascicular block	0	0	0	0	NC**
Bifascicular block	0	0	0	0	NC**
Non specific intraventricular block	3	4.8	0	0	¥p = 0.10
Repolarization changes	9	14.5	4	6.45	¥p = 0.141
Abnormal ST segment (elevation or depression)	0	0	0	0	NC**
Abnormal T waves	5	8.1	10	13.9	χ^2 = 1.137 p = 0.286
Pathological Q waves	0	0	0	0	NC**

Key: LAFB- Left anterior fascicular block, LBBB- Left bundle branch block, LPFB- Left posterior fascicular block, LVH- Left ventricular hypertrophy, NC** = Chi square statistics not computed as both cases and controls have the same proportions, PAC- Premature atrial contraction, PVC- Premature ventricular contraction, RBBB- Right bundle branch block, , RVH- Right ventricular hypertrophy, *- significant, ¥= Fisher's exact test, χ^2= chi square.

DISCUSSION:

The prevalence of ECG abnormalities in both study groups did not differ statistically. Based on the Novacode criteria, most of the abnormal ECG changes were minor (benign). The majority of the ECG abnormalities that were seen among the patient group were minor (benign) based on the Novacode criteria and this is consistent with findings from earlier researches (5, 6, 16). Likewise, there was no statistical variation in the prevalence of cardiac arrhythmias and abnormal T wave abnormalities in both study groups. This is in contrast with the study done by Kolo *et al* who reported a higher prevalence of arrhythmias and abnormal T wave patterns among patients on psychotropics, however, most of the arrhythmias were benign (16). Unlike this study, a case-control study by Chou *et al* in Taiwan found that people taking both typical and atypical antipsychotics had a significantly higher risk of developing atrial fibrillation than those who weren't taking them, indicating a causal relationship between antipsychotic medications and atrial fibrillation (17).

Sinus tachycardia was significantly more prevalent among patients taking psychiatric medications than in the control group, despite the fact that the prevalence of arrhythmias was identical in both study groups. The intrinsic atropine-like effect of tricyclic antidepressants and the anticholinergic effect of antipsychotics are the most likely mechanism of tachycardia (18, 19). It is important to note that persistent tachycardia can result in tachycardia-induced cardiomyopathy (19). In addition, the atherosclerotic process in coronary arteries had been shown to be accelerated through local hemodynamic changes when there is tachycardia (20, 21). It has been suggested that continental Africans may be more resilient to the harmful cardiovascular side effects of prolonged use of psychotropic medications than their relatives in the African American community and people of European descent (6). However, we must keep in mind that this study excluded other known cardiovascular risk factors, such as diabetes and hypertension, which are co-morbid factors acquired as patients age. Due to altered drug distribution and metabolism, as well as the potential of interactions between psychotropic and non-psychotropic medications, patients with co-morbid diseases are more likely to experience the side effects of psychotropic medications. As a result, minor ECG abnormalities that are currently noticed may eventually progress to major ECG abnormalities in the presence of other cardiovascular risk factors.

The results of the current study also revealed that those who had used psychotropic drugs had considerably higher mean QTc values ($p<0.001$). It has been previously reported that prolonged QTc is linked to a higher risk of Torsades de Pointes and sudden cardiac death (22). According to Ray *et al*, antipsychotic drug users had a 2.39-times higher risk of sudden death than 'non-users' (23).

The prevalence of ECG abnormalities differed by gender, with male patients having a considerably higher prevalence than their female counterparts ($P<0.001$). Of note is the increased prevalence of sinus bradycardia and LVH in male patients. Zerkiebel *et al* found that men had a lower heart rate than women and this has been linked to men engaging in more physical activity than women do, which results in better cardiovascular conditioning and higher vagal tone in men (24). Likewise, the higher prevalence of LVH in males has been proposed to be as a result of increased cardiac mass and left ventricular wall thickness brought on by male hormones as well as the increased geographical separation of the heart from the precordial electrodes caused by breast tissue resulting in lower QRS amplitudes in women (25). Female patient in this study had significantly higher mean QTc compared to the male patient. Female gender has been implicated as a risk factor for QTc prolongation and torsades de pointes in patients on psychotropic medications (26).

There are a few limitations of the study. Due to the study design, we were able to describe the association between psychotropic drugs and ECG abnormalities but not the cause and effect of any possible ECG abnormalities. In addition, only a resting ECG was done and hence some electrocardiographic abnormalities which will require Holter monitoring could be missed out.

CONCLUSION:

Psychotropic drugs result in abnormal ECG changes in therapeutic doses howbeit mostly benign. This study serves to provide some evidence to mental health care practitioners in limited-resources settings that though it is relatively safe to initiate and titrate psychotropic medication in an outpatient setting, however, ECG abnormalities and higher mean QTc among these patients requires that baseline ECG should be done and subsequently monitored especially in patients with other cardiovascular risk factors.

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