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Pharmacology Section

Effect of Antipsychotic Medications on ECG Parameters in Psychiatric Patients: A Cross-sectional Study

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ABSTRACT

Introduction: Antipsychotic drugs are associated with Electrocardiogram (ECG) changes at therapeutic doses, although these changes are generally benign. Several psychotropic drugs have been linked to sudden death due to their prolongation of the corrected QT (QTc) interval, which can lead to polymorphic ventricular arrhythmia.

Aim: To study the ECG changes induced by antipsychotic medications and potential Drug-Drug Interactions (DDIs) contributing to these changes in psychiatric patients.

Materials and Methods: A cross-sectional study was conducted by the Department of Pharmacology in the Outpatient Department (OPD) of Psychiatry at Maharaja Krishna Chandra Gajapati (MKCG) Medical College and Hospital, Berhampur, Odisha, India, from December 2022 to November 2023. ECGs were obtained using a 12-lead portable ECG device (Spandan) in each case. Potential DDIs that may cause QTc prolongation were assessed using the Lexicomp® tool.

Results: A total of 205 psychiatric patients were included in the present study, of which 142 (69%) were males and 31% (n=63) were females, with a mean age of 42.4±14.64 years. A total of 82 patients (40%) exhibited some ECG abnormalities. Among these abnormalities, 40% displayed abnormal ST/T changes, followed by 36% with QTc prolongation, and 16% with abnormal heart rates. Among the antipsychotics, haloperidol (p=0.037) showed a significant association with QTc changes. Female sex (p=0.027) was identified as a significant risk factor associated with QTc changes. The drug combinations with the highest potential for causing QTc changes were Olanzapine+Escitalopram (25%), followed by Haloperidol+Olanzapine (16%) The association of drugs with ECG changes and risk factor associations were analysed using the Chi-square test and odds ratio.

Conclusion: The use of psychotropic drugs may be associated with ECG changes at usual doses. Therefore, psychiatric patients should be evaluated for ECG abnormalities prior to the initiation of antipsychotic medications to avoid potential cardiovascular complications. Regular medication reviews are also necessary to identify and prevent potential drug-drug interactions.

Keywords: Electrocardiogram, Potential drug-drug interaction, QTc prolongation, ST/T abnormalities

INTRODUCTION

Antipsychotic drugs are associated with ECG changes at therapeutic doses, and most of these changes are benign in nature [1]. Some studies have reported that psychiatric patients are at risk for cardiovascular problems [2,3]. Mortality rates are higher in psychiatric patients, which may be attributed to the adverse effects of antipsychotic medications. Certain cardiovascular risk factors, such as smoking, lack of exercise, obesity, substance misuse, and high autonomic arousal during physical restraint, are overrepresented in psychiatric patients [1].

In recent years, there has been increasing concern about the cardiovascular safety of psychotropic drug treatments [1]. However, the risk of drug-induced Torsades de Pointes (TdP) can increase under several conditions, including structural heart disease, electrolyte abnormalities, hypothyroidism, pre-existing QT prolongation, QT dispersion, sinus bradycardia, and polymorphic ventricular premature beats [1]. Several psychotropic medications have been associated with sudden death due to their effect on prolonging the QT interval, resulting in the development of TdP [4,5].

Previous research has identified several factors that can lead to QTc prolongation, such as being over 65 years old, female sex, and the use of tricyclic antidepressants (TCAs) and/or antipsychotics. Other factors include the dosage of antipsychotics, the presence of bradycardia, electrolyte imbalances, and genetic predisposition [4].

One study showed no significant changes in ECG parameters after the short-term administration of antipsychotic drugs like olanzapine, risperidone, trifluoperazine, and haloperidol [3]. Treatment with antipsychotics is linked to the development of Cardiovascular Diseases (CVDs) [6]. A particular study found that antipsychotics such as thioridazine, ziprasidone, and intravenous haloperidol at high doses are associated with the highest risk of a long QTc interval (LQTc) and/or TdP [7].

Antipsychotics like quetiapine and amisulpride, along with most tri- and tetracyclic antidepressants, SSRIs (such as citalopram, fluoxetine, and paroxetine), and venlafaxine, have also been associated with TdP. Although the prevalence rates of polypharmacy in psychiatry vary between 13% and 90%, few studies have investigated the effects of psychotropic drug combinations on the ECG [5,8,9].

According to the literature available to date, no studies have been conducted in Odisha, and very few studies are available in India. Against this background, the present study was undertaken to investigate the ECG changes associated with antipsychotic medication. Hence, the objectives of the present study was to identify the types of changes in ECG parameters due to antipsychotic drugs, to determine the association between the type of drug and ECG changes; and to identify potential Drug-drug Interactions (DDIs) that may lead to ECG changes.

MATERIALS AND METHODS

A cross-sectional study was conducted by the Department of Pharmacology in the Outpatient Department of Psychiatry at Maharaja Krishna Chandra Gajapati (MKCG) Medical College

and Hospital, Berhampur, Odisha, India, from December 2022 to November 2023. Ethical clearance for the study was obtained from the Institutional Ethics Committee (IEC) at MKCG Medical College with approval number 1369/IEC/MKCG Medical College.

Inclusion criteria: The inclusion criteria comprised patients diagnosed with psychiatric disorders or those under antipsychotic drug treatment who came to the OPD for follow-up. Patients needed to be able to answer questions. The study included participants above 18 years of age of all genders who were willing to participate and provided written informed consent.

Exclusion criteria: The exclusion criteria included aggressive patients, patients with severe forms of disease, substance abuse, or those not taking medications regularly. Patients who could not cooperate for the ECG or did not answer the questions asked were also excluded. Additionally, any patients with a history of cardiovascular disease before the diagnosis of psychiatric illness or pregnant women were excluded.

Sample size calculation: The sample size for the study was calculated using Statulator, an online statistical calculator. The prevalence of mental illness in India (P) is 13.7% [10]. Using this prevalence rate, a 95% Confidence Level (CL), and an absolute precision of 0.05, the sample size (n) was calculated as 186. After accounting for a 10% non response rate, the final sample size was set at 205.

Sampling Method: Convenience sampling was employed.

Study Tools Used:

- Credible Medical Drug List (QT Prolongation)/Arizona Centre for Education and Research on Therapeutics Classification (AZCERT)Classification [11]
- DDIs Checker: Lexicomp® Drug Interaction Tool [12]
- Portable ECG Device "Spandan" [13,14]

Credible med drug list (QT prolongation)/AZCERT classification [11]

Known risk of TdP: These drugs prolong the QTc interval and are clearly associated with a known risk of TdP, even when taken as recommended.

Possible risk of TdP: These drugs can cause QT prolongation but currently lack evidence for a risk of TdP when taken as recommended.

Conditional risk of TdP: These drugs are associated with TdP, but only under certain conditions of their use (e.g., excessive dosing, in patients with conditions such as hypokalemia, or when taken with interacting drugs), or by creating conditions that facilitate or induce TdP (e.g., by inhibiting the metabolism of a QT-prolonging drug or by causing an electrolyte disturbance that induces TdP).

Study Procedure

Data regarding sociodemographic characteristics such as age, sex, marital status, and co-morbid conditions were recorded in a predesigned case record form. ECG changes associated with antipsychotic drugs were assessed, and potential drug-drug interactions leading to ECG abnormalities were documented. On the day of enrollment, the above data was collected from treatment records and by asking questions to the patient or attendant. On the same day, the patient underwent ECG testing using a 12-lead portable ECG machine ("Spandan device"). The types of changes in the ECG were recorded in the case record form with confirmation by expert opinion. QT intervals were corrected for heart rate using Bazett's formula ($QTc=QT / \sqrt{RR}$) and were manually interpreted by a trained technician to ensure accuracy. Potential DDIs that may cause QTc prolongation were calculated using the Lexicomp® tool and expressed in frequency and percentages.

STATISTICAL ANALYSIS

Data were entered into Microsoft Excel and compiled for analysis using statistical software Statistical Package for the Social Sciences (SPSS) version 22.0. Categorical data were analysed using descriptive statistics and expressed in frequency and percentage. The association of drugs with ECG changes and risk factor associations were analysed using the Chi-square test and odds ratio. A p-value <0.05 was considered statistically significant.

RESULTS

The sociodemographic parameters of study participants (N=205) are depicted in [Table/Fig-1]. The data shows that 50% of patients were within the age group of 18-40 years, with a mean age of 42.4±14.64 years, indicating a male preponderance (69%).

Parameters	n (%)
Age (in years)	
18-40	102 (50%)
41-60	74 (36%)
>60	29 (14%)
Gender	
Male	142 (69%)
Female	63 (31%)
Dependency in daily functioning/living	
Dependent	157 (76%)
Independent	48 (24%)
Co-morbidity	
Yes	33 (16%)
No	172 (84%)
Marital status	
Married	62 (30%)
Unmarried	119 (58%)
Widowed	24 (12%)
Sedentary lifestyle	
Yes	98 (48%)
No	107 (52%)

[Table/Fig-1]: Distribution of sociodemographic characteristics (N=205).
*Data expressed with frequency and percentage

As per [Table/Fig-2], among the present study population, the majority, 90 cases (44%), were diagnosed with schizophrenia, followed by bipolar affective disorder (23%).

Type of clinical cases	n (%)
Schizophrenia	90 (44%)
Bipolar affective disorder	47 (23%)
Unspecified psychosis	25 (12%)
Major depressive disorder	10 (4%)
Somatoform disorder	11 (5%)
Post Traumatic Stress Disorder (PTSD)	03 (1%)
Atypical depression	04 (2%)
Generalised Anxiety Disorder (GAD)	06 (3%)
Others	09 (4%)

[Table/Fig-2]: Distribution of clinical cases under antipsychotic drugs (N=205).
*Data expressed with frequency and percentage
†Others (Alzheimer's with behavioural and psychological symptoms of dementia, phobic anxiety disorder, severe stress and adjustment disorder)

The ECG changes were found in 82 patients (40%). The study results indicated that out of a total number of ECG changes (n=101), the highest proportion was ST/T changes (ST elevation, ST depression, or both and T wave inversion), at 40%, followed by QTc prolongation in 36% of cases [Table/Fig-3].

There were 12 DDIs identified using the Lexicomp® tool that may result in an increase in the QTc interval. The combination

with the highest potential for causing QTc prolongation was olanzapine+escitalopram (25%), followed by haloperidol+olanzapine (16%) and quetiapine+escitalopram (13%) as per [Table/Fig-4].

ECG changes	n (%)
QTc prolongation	36 (36%)
ST/T changes	41 (40%)
Incomplete RBBB	04 (4%)
Premature atrial contraction	04 (4%)
Heart rate changes (Tachycardia / Bradycardia)	16 (16%)

[Table/Fig-3]: Distribution of different types of ECG changes (n=101).
*Data expressed with frequency and percentage

PDDI	n (%)
Amisulpride + Escitalopram	1 (1%)
Amisulpride + Haloperidol	2 (3%)
Amisulpride + Olanzapine	7 (9%)
Amisulpride + Quetiapine	2 (3%)
Amisulpride + Clozapine	4 (5%)
Olanzapine + Escitalopram	19 (25%)
Quetiapine + Escitalopram	10 (13%)
Haloperidol + Olanzapine	12 (16%)
Olanzapine + Quetiapine	5 (7%)
Olanzapine + Risperidone	5 (7%)
Quetiapine + Risperidone	3 (4%)
Haloperidol + Lithium	5 (7%)

[Table/Fig-4]: Distribution of potential drug combinations used may lead to QTc prolongation (According to Lexicomp® tool) (n=75).
*Data expressed with frequency and percentage

Female sex was identified as a significant risk factor associated with QTc changes in the present study [Table/Fig-5]. Patients treated with haloperidol who developed QTc prolongation were found to be significantly associated compared to those receiving other drug treatments [Table/Fig-6].

Risk factors	QTc changes	Chi-square	p-value	OR	CL
Female sex (n=63)	17 (27%)	5.575	0.027*	2.017*	(1.126-3.613)
Co-morbidity (n=33)	8 (24%)	1.213	0.317	0.672	(0.336-1.314)
Sedentary life style (n=98)	18 (18%)	0.84	0.855	0.916	(0.506-1.657)

[Table/Fig-5]: Risk factors associated with QTc changes caused by psychotropic drugs.
*indicates the female sex had significant risk association with QTc prolongation
†Data expressed with frequency and percentage and risk association was done by Chi-square test and Odds ratio.

According to [Table/Fig-7], following the AZCERT classification, 53 (10%) of the prescribed medications fell under the known risk category, 31 (6%) under the possible risk category, 236 (44%) under the conditional risk category, and 216 (40%) were not categorised under any of these three categories for TdP.

DISCUSSION

The present study found that out of a total of 205 study participants, the largest proportion (50%) fell within the age range of 18-40 years, followed by 41-60 years (36%), and 14% were over 60 years. This finding is consistent with a previous study conducted by Moosa MY et al., in 2004 [15]. This similarity may be attributed to the life transitions experienced by individuals within these age brackets. Individuals in this age range often face significant life changes, such as career shifts, marriage, or parenthood, which can exert considerable stress and potentially impact an individual's mental well-being.

In the present study, females constituted 31% of the total study population, which is lower than the findings of Hefner G et al., (44%) [16], Girma B et al., (2021) (40%) [6], Wong S et al., (40%) [2], Kinagi S et al., (55%) [1], and Moosa MY et al., (55%) [15]. These

Drugs	QTc pro-longed	Chi-square value	p-value	Odds ratio	CI
Haloperidol (23)	8	5.307	0.037*	2.26	1.174-4.353
Olanzapine (120)	21	0.01	1	0.992	0.543-1.810
Quetiapine (26)	6	0.626	0.4	1.3	0.635-2.98
Risperidone (32)	4	0.671	0.613	0.676	0.25-1.76
Clozapine (10)	3	1.124	0.385	1.773	0.644-4.802
Amisulpride (39)	6	0.158	0.817	0.851	0.381-1.902
Aripiprazole (3)	1	0.523	0.44	1.924	0.37-9.8

[Table/Fig-6]: Antipsychotic drugs associated with QTc prolongation (n=253).
*indicates the drug haloperidol had significant risk association with QTc prolongation.
†Data expressed in number and risk association was done by Chi-square test and Odds ratio.

QTc/TdP Risk categories	Drugs	n (%)
Known risk	Haloperidol	23 (4%)
	Escitalopram	30 (6%)
Possible risk	Clozapine	10 (2%)
	Aripiprazole	3 (0.6%)
	Flupentixol	2 (0.4%)
	Lithium	15 (3%)
	Mirtazapine	1 (0.2%)
Conditional risk	Quetiapine	26 (5%)
	Olanzapine	120 (22%)
	Risperidone	32 (6%)
	Amisulpride	39 (7.3%)
	Sertraline	19 (3.5%)
Not classified	Divalproex Sodium	59 (11%)
	Duloxetine	4 (0.7%)
	Clonazepam	141 (26%)
	Nitrazepam	5 (1%)
	Lorazepam	7 (1.3%)

[Table/Fig-7]: Distribution of psychotropic drugs prescribing according to AZCERT Classification/Credible medical list (n=536).
RBBB: Right bundle branch block Data expressed with frequency and percentage

differences in findings may stem from sociocultural variations within study populations, methodologies, and data analysis techniques.

It was found that 76% of subjects were financially dependent on their family members for their livelihood, which aligns with the results of a systematic review by Bartelink VHM et al., (2020). They also found an association between unemployment among young individuals and mental health [17]. Approximately 16% of patients had additional comorbid conditions, such as diabetes mellitus, hypothyroidism, and epilepsy. This percentage of co-morbidity in our study is slightly lower than that reported by Kinagi S et al., (23.7%) [1].

Approximately 48% of patients were found to lead a sedentary lifestyle in the present study, indicating a relationship between excessive sedentary behaviour, inadequate physical activity, and an increased risk of developing psychiatric disorders. This is consistent with a study conducted by Ba H et al., (2024), which established a causal link between a sedentary lifestyle and psychiatric disorders [18].

Among the study population, the majority 90 (44%) were diagnosed with schizophrenia as illustrated in [Table/Fig-2].. This finding is consistent with the study conducted by Girma B et al., in 2021, which reported a rate of 42.5% [6]. Bipolar affective disorder was the second most common diagnosis, accounting for 23% of cases. According to Yamada Y et al., schizophrenia and bipolar disorder frequently overlap in terms of symptoms, familial patterns, outcomes, and treatment responses [19].

A total of 82 patients (40%) exhibited ECG changes out of the 205 cases under treatment in the present study. This figure is lower than

that reported by Moosa MY et al., in Johannesburg (67.5%) [15], Kinagi S et al., in 2014 (67.5%) [1], Girma B et al., in Ethiopia in 2021 (60%) [6], and Tirupati S and Gulati S (52%) [20]. However, it is higher than the results of two studies conducted in Switzerland, which reported ECG changes in 27.3% [21] and 17.9% [22] of the participants.

The inconsistencies in the prevalence rate of ECG abnormalities may be due to various factors such as geographical location, sample size, study design, inclusion criteria, drug prescribing patterns, and criteria for defining ECG abnormalities, which may differ among studies [1,6]. As per [Table/Fig-3], among the ECG changes, ST/T changes (40%) were observed in the present study, which is comparable to the findings of Moosa MY et al., (36%) [15] and Kinagi S et al., (35.9%) [1], and higher than that reported by Girma B et al., in 2021 (24.6%) [6].

The use of psychotropic drugs can lead to the inhibition of rapid sodium currents generated by the type V α-subunit of the voltage-gated sodium channel. This inhibition results in a decrease in maximum sodium entry, causing changes in voltage gradients that manifest as ST elevation on the ECG [6]. Increased activity of the sympathetic nervous system and the impact of antipsychotic medications on blood potassium levels may account for the T-wave changes seen in psychiatric patients. Antipsychotics are thought to lead to low potassium levels due to alterations in adrenergic signaling. It has been suggested that an increased adrenergic state could activate beta-2 receptors, leading to potassium moving into skeletal muscle cells, which may result in a decrease in blood potassium levels [6].

Among the changes observed in ECGs, QTc prolongation was found in 36%, which is higher than the results of the study conducted by Kinagi S et al., in 2014 (8.2%) [1], the study by Ansermot N et al., in 2019 in Switzerland (7.6%) [21], the study by Moosa MY et al., in Johannesburg (8.2%) [15], and the study by Girma B et al., in 2021 in Ethiopia (19.4%) [6].

Several factors may limit the comparison across studies, such as heterogeneity in cut-off values for defining QTc prolongation, different study designs, characteristics of participants, inclusion and exclusion criteria, sociodemographic parameters, and the presence or absence of comorbidities, age, and race across regions [21]. Numerous psychotropic medications obstruct the human ether-à-go-go-related gene (hERG) voltage-gated potassium channels, which play a crucial role in the repolarization of the cardiac action potential. This obstruction can lead to a prolongation of the QTc interval on an ECG, potentially triggering malignant polymorphic ventricular tachycardia, also known as torsades de pointes, accompanied by syncope and sudden death, as shown in similar studies by Glassman AH and Bigger JT (2001) [23].

Regarding other types of alterations in ECG in the present study, heart rate fluctuations, specifically sinus tachycardia or sinus bradycardia, accounted for 16% of the total changes observed. This figure is slightly lower than that reported in other studies by Moosa MY et al., (28.8%) [15], Kinagi S et al., (28%) [1], and Girma B et al., (19.7%) [6]. In this study, only 4% of the patients exhibited incomplete Right Bundle Branch Block (RBBB), which aligns with the findings of a study conducted by Girma B et al., in 2021 [6].

The use of psychotropic medications, particularly antipsychotics and Tricyclic Antidepressants (TCAs), can result in the blockage of sodium ion channels. This action leads to a reduction in the inward current of sodium ions, resulting in conduction delays, atrioventricular blocks, and bundle-branch blocks [6].

There are 12 DDIs identified using the Lexicomp® tool that may result in an increase in the QTc interval. The combination with the highest potential for causing QTc changes is olanzapine+escitalopram (25%), followed by haloperidol+olanzapine (16%) and quetiapine+escitalopram (13%). However, the present study results differ from those of Das B et al., at AIIMS Rishikesh [24], where the combination of escitalopram+risperidone (11.5%) had the highest potential for causing DDI, followed by escitalopram+olanzapine (11.1%). This difference in results may be attributed to the use of different tools and methods for evaluating potential DDIs.

According to the AZCERT classification/Credible Med list, 10% of prescribed medications fall under the known risk category for Torsades de Pointes (TdP), which is slightly lower compared to studies conducted by Ansermot N et al., in 2019 [21] (28.2%), Das B et al., in 2021 [24] (48.8%), and Hefner G et al., [16] (37%). Additionally, 6% of prescribed medications fall under the possible risk category for TdP, which is also slightly lower compared to the aforementioned studies (38.9%, 34.8%, and 27%, respectively). Lastly, 44% of prescribed medications fall under the conditional risk category for TdP, which is slightly higher than the study conducted by Ansermot N et al., [21] in 2019 (38.4%) and Das B et al., [24] in 2021 (12%).

Limitation(s)

The study was conducted at a single centre, which may limit the generalisability of the findings. As this is a cross-sectional study, a cause-effect relationship has not been established, as there were no baseline ECG recordings before the commencement of antipsychotics, no comparator groups, and no multiple prospective ECG recordings. Many psychiatric patients were concurrently treated with other psychotropic medications, making it difficult to attribute the observed ECG changes solely to antipsychotic drugs. Despite excluding known cardiovascular disease, subclinical or undiagnosed cardiac conditions may have contributed to ECG abnormalities.

CONCLUSION(S)

Based on the results of the present study, it can be suggested that patients with psychiatric diseases should undergo ECG evaluation prior to starting antipsychotic medications to avoid the risk of cardiovascular complications. There may be a need for ECG monitoring for patients taking drugs classified under known or potential risk categories for TdP. It is imperative to use these medications with caution, adhering to standard dosing guidelines and avoiding concomitant use with other QTc-prolonging agents in cases of conditional risk to mitigate the risk of TdP. Regular medication reviews are also required to identify and prevent potential DDIs.

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