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ORIGINAL ARTICLE

Effects of Hydroxychloroquine Treatment on QTc Interval in COVID-19 Positive Patients with Schizophrenia

COVID-19 Pozitif Şizofreni Hastalarında Hidroksiklorokin Tedavisinin QTc Aralığı Üzerindeki Etkileri

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ABSTRACT

Aim: The effect of hydroxychloroquine (HCQ) treatment on the corrected QT interval (QTc) in COVID-19-positive schizophrenia patients was a significant topic of discussion at the beginning of the pandemic. While the efficacy of HCQ remains controversial, severe cardiac side effects such as QTc prolongation can potentially lead to life-threatening arrhythmias. This study aims to investigate the potential impact of HCQ on QTc prolongation when used in combination with antipsychotic medications.
Materials and Methods: This retrospective study includes 25 schizophrenia patients diagnosed with COVID-19 and undergoing antipsychotic treatment. Electrocardiographic (ECG) data obtained during routine follow-up were retrospectively evaluated. The dose management of antipsychotic drugs during treatment was analyzed. A QTc interval of 500 ms or longer was considered the pathological threshold.
Results: A significant prolongation of the QTc interval was observed on the 3rd and 5th days of HCQ treatment, as well as on the first day after discontinuation, compared to the QTc intervals recorded at hospital admission ($p < 0.05$). Gender-based analysis revealed that significant QTc changes were observed only in female patients on the 2nd and 3rd days of HCQ treatment ($p < 0.05$). In cases where QTc prolongation occurred, no common characteristics were identified in terms of medications used, clinical diagnoses, or comorbid conditions.
Conclusion: The potential QTc prolongation associated with HCQ use is considered a significant risk factor for ventricular fibrillation and sudden cardiac arrest. The combination of HCQ with antipsychotic medications may lead to potentially life-threatening cardiac side effects. Therefore, regular monitoring of cardiac electrical activity, particularly QTc interval, is critically important.

Keywords: Antipsychotics, COVID-19, hydroxychloroquine, QTc interval, schizophrenia

ÖZ

Giriş: COVID-19 pozitif şizofreni hastalarında hidroksiklorokin (HCQ) tedavisinin corrected QT interval (QTc) aralığı üzerindeki etkisi, pandeminin başlangıcında önemli bir tartışma konusu olmuştur. HCQ'nun etkinliği halen tartışmalı olmakla birlikte, QTc uzaması gibi ciddi kardiyak yan etkileri potansiyel olarak hayatı tehdit eden aritmilere yol açabilmektedir. Bu çalışmanın amacı, HCQ'nun antipsikotik ilaçlarla birlikte kullanıldığında QTc uzaması üzerindeki potansiyel etkisini araştırmaktır.
Gereç ve Yöntemler: Bu retrospektif çalışma, COVID-19 tanısı almış ve antipsikotik tedavi gören 25 şizofreni hastasını içermektedir. Takip sürecinde rutin olarak elde edilen elektrokardiyografik (EKG) veriler retrospektif olarak değerlendirilmiştir. Tedavi sürecinde antipsikotik ilaçların doz yönetimi analiz edilmiştir. QTc aralığının 500 ms ve üzerinde olması patolojik sınır olarak kabul edilmiştir.
Bulgular: HCQ tedavisinin 3. ve 5. günlerinde ve tedavinin kesildiği ilk gün, hastaneye yatış sırasında kaydedilen QTc aralıklarıyla karşılaştırıldığında, QTc aralığında anlamlı bir uzama olduğu belirlenmiştir ($p < 0.05$). Cinsiyete göre yapılan analizde, QTc aralığında anlamlı değişiklik yalnızca kadın hastalarda HCQ tedavisinin 2. ve 3. günlerinde gözlemlenmiştir ($p < 0.05$). QTc uzaması gelişen olgularda, kullanılan ilaçlar, klinik tanı veya eşlik eden hastalıklar açısından ortak bir özellik saptanmamıştır.
Sonuç: HCQ kullanımına bağlı olası QTc uzaması, ventriküler fibrilasyon ve ani kardiyak arrest açısından önemli bir risk faktörü olarak değerlendirilmektedir. HCQ'nun antipsikotik ilaçlarla birlikte uygulanması, potansiyel olarak yaşamı tehdit edebilecek kardiyak yan etkilere yol açabilmektedir. Bu nedenle, özellikle QTc aralığı başta olmak üzere kardiyak elektriksel aktivitenin düzenli olarak izlenmesi kritik öneme sahiptir.

Anahtar Kelimeler: Antipsikotikler, COVID-19, hidroksiklorokin, QTc aralığı, şizofreni

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) caused a pandemic in 2019, leading to significant economic and social issues worldwide (1). At the beginning of the pandemic, the absence of a vaccine to prevent COVID-19 and the lack of an established treatment protocol led to the exploration of alternative therapeutic options. Among these alternatives, chloroquine (CQ) and hydroxychloroquine (HCQ), drugs that have been used for many years in the treatment of malaria, were reported as potentially good options that could be effective in treatment. Although primarily used to prevent and treat malaria, HCQ and CQ were also used in the treatment of rheumatoid arthritis, lupus, and porphyria cutanea tarda and were among the first off-label approved drugs for COVID-19 treatment. Regarding HCQ effectiveness and safety, a growing number of studies have been published with conflicting results (2).

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The prolongation of the corrected QT interval (QTc), an electrocardiographic parameter reflecting ventricular repolarization, is a key indicator of cardiac risk. A prolonged QTc interval can result in severe consequences, including Torsades de Pointes, ventricular fibrillation, and sudden cardiac arrest. This risk may be further exacerbated when QTc-prolonging medications, such as certain first-generation antipsychotics, are used concurrently(3). The simultaneous use of antipsychotics and HCQ has raised concerns regarding proper management. While previous studies have primarily focused on the general cardiac side effects of HCQ, the specific risks in COVID-19-positive schizophrenia patients - a particularly vulnerable group - have not been thoroughly investigated. It is well established that antipsychotics, particularly first-generation agents such as chlorpromazine and haloperidol, negatively affect cardiac rhythm conduction and significantly prolong the QTc interval (3). In patients with pre-existing QTc prolongation, this can substantially increase the risk of life-threatening arrhythmias, including ventricular fibrillation(4).

The primary objective of this study is to assess the impact of HCQ treatment on QTc intervals in schizophrenia patients with COVID-19, particularly in combination with antipsychotics, and to evaluate the potential risks associated with QTc prolongation. Additionally, changes in QTc intervals following the concurrent use of antipsychotics with HCQ, azithromycin, and favipiravir were documented. The treatment strategy and COVID-19 management algorithm were retrospectively analyzed, taking into account comorbid conditions that could influence QTc intervals.

Materials and Methods

Subjects and Procedures

This retrospective study was conducted on patients with schizophrenia spectrum disorders (n=25), including 10 females and 15 males, diagnosed with COVID-19. Patients with other psychiatric comorbidities or conditions such as multi-organ failure, treatment-resistant electrolyte imbalances, known cardiac arrhythmia, heart failure, previous cardiac surgery, or those on ongoing antiarrhythmic medications were excluded from the study. Biochemical tests (whole blood and routine biochemistry) and radiological tests (chest computerized tomography) were conducted, and infection with the SARS-CoV-2 virus was confirmed via PCR testing during initial hospitalization.

Patients were categorized according to the World Health Organization (WHO) severity scale (mild, moderate, severe, critical). The association between disease severity and QTc prolongation was examined; however, no significant correlation was identified. Antipsychotic doses were managed based on chlorpromazine equivalent doses before the initiation of HCQ treatment. To prevent possible QTc prolongation, antipsychotic doses were reduced to half of the normal dose in hospitalized patients. All patients received five days of HCQ treatment according to the COVID-19 guidelines issued and updated by the Turkish Republic Ministry of Health Science Board. According to the guidelines, when additional treatment was required, azithromycin (n = 8) and favipiravir (n=1) were administered.

Electrocardiographic measurements were taken before treatment and during the five-day follow-up period using the same General Electric (GE) device (Model: MAC200), and again seven days after discontinuation of HCQ treatment. A follow-up ECG was performed on Day 7 after HCQ discontinuation as part of routine monitoring to evaluate potential late-onset QTc prolongation, per institutional protocol. QTc intervals of 470 ms in females and 450 ms in males were considered the upper limit, with longer QTc intervals considered pathological. QTc intervals of more than 500 ms were considered potentially life-threatening, possibly causing severe arrhythmias in both genders. QTc intervals measured before HCQ treatment were compared with those during the five-day treatment period and the seven days following the completion of HCQ treatment.

Statistical Analyses and Ethics

All data were expressed as mean ± standard error of the mean (SEM). QTc intervals were compared using Student's t-test for paired samples, and a Bonferroni correction was applied to account for experiment-wise error due to multiple comparisons. The correlations between daily QTc intervals and the chlorpromazine-equivalent doses of the antipsychotics were calculated using Pearson's test. The sample size was determined using G*Power v3.1.9.4, and it was estimated that 23 patients would be required to achieve adequate power (0.80) with an estimated effect size (d=0.82). Statistical significance was set at $p < 0.05$. The local institutional ethics board at Ankara City Hospital approved this study (June 25th, 2020,

#E1-20-773), and approval was obtained from the Turkish Ministry of Health (Approval certificate number: 2020-05-13T22-06-22).

Electrocardiographic Measurements

ECG measurements were obtained using a General Electric MAC200 device, which is known for its reliability and precision in capturing cardiac electrical activity. Standard settings for the device included a recording speed of 25 mm/s and an amplitude of 10 mm/mV, both of which are widely recognized for ensuring accurate waveform representation. The QTc intervals were calculated using Bazett's formula, a commonly used method for correcting the QT interval for heart rate. The visual showing the QTc measurement has been included in Figure 3.

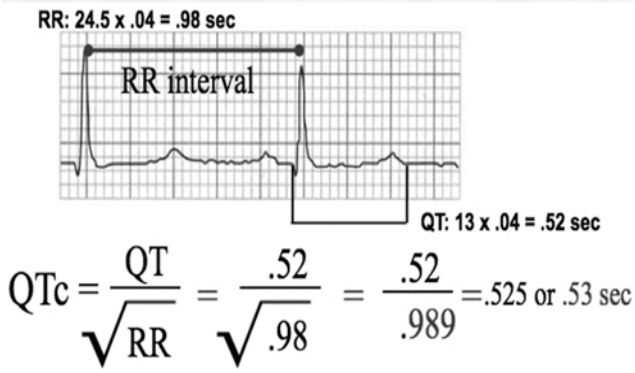

Figure 3. The visual shows the, P wave, QRS complex, and T wave, with markers highlighting the QT interval and the QTc calculation, including Bazett's formula

Results

The patients were 48.64±2.24 years old, with no significant difference in age between male and female patients (p >0.05; males: 51.27±3.03 vs females: 44.70±3.02 years). The patients were treated with several atypical antipsychotic drugs (n=11, olanzapine; n=6, risperidone; n=3, aripiprazole; n=3, quetiapine; n=1, clozapine; n=1, paliperidone). The mean chlorpromazine equivalent dose was calculated as 427.31±66.99 mg/day.

The results of the QTc intervals are presented in Table 1, and Figures 1 and 2. According to the data, QTc intervals exceeded the upper limit between the 3rd and 5th days of HCQ treatment, and on the first day after HCQ discontinuation, compared to the baseline QTc recorded at initial admission (p <0.05; Figure 1). Since the upper limits of QTc prolongation differ between men and women, these two groups were evaluated separately in the next stage. The QTc duration upper limits are 470 ms for women and 450 ms for men. HCQ treatment significantly increased QTc durations on the 2nd and 3rd days of the treatment period compared to baseline levels (p <0.05, Figure 2). The difference in QTc duration compared to baseline reached statistically significant levels only in women and on the 2nd and 3rd days of HCQ treatment (p <0.05, Figure 2).

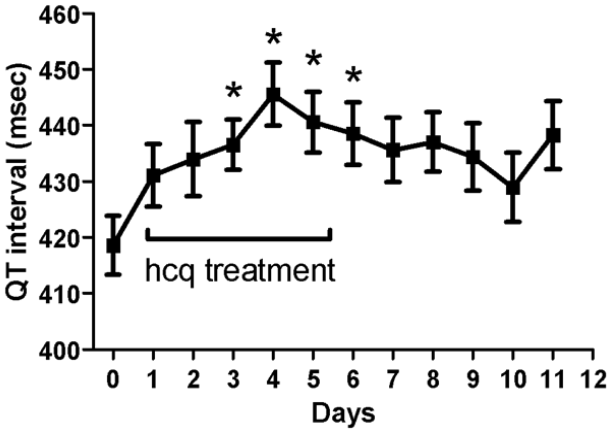

Figure 1. QTc intervals exceeded the upper limit between 3rd and 5th days

Table 1. QTc Interval (msec) of the patients categorized according to sex.

	All the patients (n=25)			Male (n=15)			Female (n=10)		
Days	Mean±SD	Median	Min-Max	Mean±S.D.	Median	Min-Max	Mean±SD	Median	Min-Max
0	418.56±26.28	415.0	355-469	414.60±26.57	410.0	355-460	424.50±24.67	419.5	391-469
1 (HCQ)	431.08±27.24	430.5	366-479	426.07±31.40	416.5	366-479	438.10±17.76	438.5	411-471
2 (HCQ)	433.96±33.04	438.0	349-492	427.73±29.01	433.0	378-478	443.30±36.36*	452.0	349-492
3 (HCQ)	436.54±21.96*	434.5	377-488	431.86±22.38	432.0	377-466	443.10±19.57*	435.0	421-488
4 (HCQ)	445.58±27.50*	447.5	385-497	440.36±23.58	447.5	385-473	452.90±30.74	457.5	402-497
5 (HCQ)	440.60±27.06*	443.0	393-492	433.07±23.82	432.0	393-486	451.90±27.67	453.0	400-492
6	438.52±26.75*	441.0	392-495	429.36±20.43	430.0	392 - 464	452.78±29.07	453.0	393-495
7	435.63±28.22	442.0	382-479	431.64±26.46	437.0	390-472	441.20±29.64	450.5	382-479
8	437.04±26.11	442.0	348-480	431.71±27.50	442.0	348-469	444.50±21.96	445.0	411-480
9	434.36±28.27	435.5	385-484	431.00±25.70	435.5	385-471	440.25±31.44	438.0	400-484
10	428.94±26.16	432.0	378-481	426.70±19.03	430.5	392-457	431.75±32.75	439.5	378-481
11	438.27±23.44	447.0	389-467	430.22±22.91	430.0	389-467	450.33±18.54	457.5	411-465

SD: Standard deviation, Min-Max: Minimum-Maximum. (HCQ, hydroxychloroquine treatment; *p <0.05, Student's t-test for paired samples).

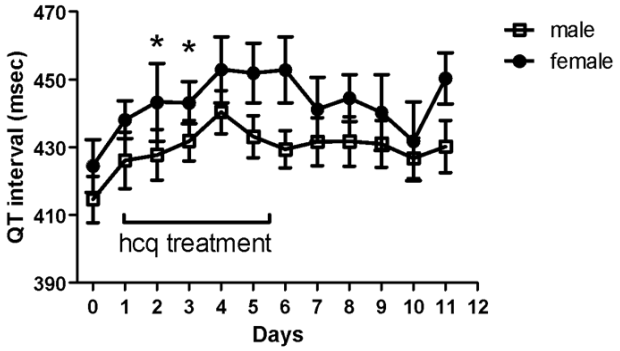

Figure 2. Significant difference in QTc durations on the 2nd and 3rd days after HCQ initiation

The mean±SEM values of QTc intervals did not exceed 450 ms in men or 470 ms in women while patients were followed up in the clinic. Upon individual analysis, cases that occasionally exceeded the borderline showed no common characteristics in terms of drug use, clinical diagnosis, or comorbidities, and these patients exhibited no clinical signs or symptoms. The correlations between QTc intervals and chlorpromazine equivalent doses are presented in Table 2. No significant correlations were observed between these variables.

Table 2. Correlation coefficients and significance levels between chlorpromazine equivalent doses of antipsychotic drugs and QTc intervals

	Days											
	0	1	2	3	4	5	6	7	8	9	10	11
r	0,264	-0,090	0,288	0,066	0,102	0,022	-0,071	0,005	-0,002	-0,429	0,129	0,301
p	0,212	0,682	0,173	0,763	0,643	0,918	0,754	0,982	0,991	0,053	0,623	0,295

Discussion

In the present study, we showed that QTc intervals exceeded the upper limit on the 3rd and 5th days of HCQ treatment, as well as on the first day after discontinuing HCQ, compared to QTc intervals recorded at initial hospital admission ($p < 0.05$). In addition to that significant difference in QTc intervals only in women was seen on the 2nd and 3rd days of HCQ treatment ($p < 0.05$). The present study indicated that patients need to be monitored more closely for QTc prolongation to prevent potential life-threatening side effects when HCQ treatment is administered alongside antipsychotic drugs. QTc prolongation may be associated with the number of antipsychotic drugs prescribed concurrently or with drugs that can cause QTc prolongation, such as HCQ. All drugs that prolong the QTc interval, when prescribed with antipsychotics, should be thoroughly evaluated. Dose adjustments and close monitoring are essential when concurrent use with HCQ is necessary, as failure to do so could lead to life-threatening problems such as ventricular fibrillation or death (5).

According to a randomized clinical study conducted on a large group of patients, a higher dose of HCQ is associated with potentially life-threatening QTc prolongation, especially when taken with azithromycin and oseltamivir (6). The potential risk factor for QTc prolongation with HCQ was identified as doses exceeding 1200 mg/day for 10 days. However, in the present study, HCQ was administered at a loading dose of 800 mg/day on the first day, followed by a reduced dose of 400 mg/day. Therefore, our procedure differed from the studies we compared with. Additionally, our study group consisted of younger patients (average age: 48.6 vs. 54.7 years).

Another study indicated that HCQ-induced QTc prolongation in COVID-19 patients, with 500 ms being considered the pathological limit. Takla & Jeevaratnam (7) reported that among the total studies investigating cardiac side effects, 44% identified an increased incidence of QTc prolongation and/or arrhythmias. Furthermore, the addition of azithromycin was associated with more pronounced changes in QTc. A recently published study demonstrated that HCQ/azithromycin treatment led to QTc interval prolongation, with a subset of patients developing a QTc interval exceeding 500 ms (8).

There is evidence suggesting that the effects of HCQ and azithromycin on QTc intervals vary by sex. In a study conducted by Grewal et al (9) female COVID-19 patients exhibited longer mean QTc intervals in two of the three cohorts analyzed. The greater QTc prolongation observed in female COVID-19 patients may be attributed to hormonal differences. Estrogen is known to influence cardiac repolarization, and it is hypothesized that the observed sex-related difference in QTc intervals may result from estrogen-mediated inhibition of potassium channels. The available data suggest that female COVID-19 patients may be more

susceptible to the effects of these drugs, with more pronounced QTc prolongation compared to their male counterparts.

In a separate study evaluating the safety of the azithromycin/ HCQ combination, it was reported that 21% of patients experienced QTc prolongation exceeding 500 ms. A retrospective analysis was performed to investigate the factors contributing to this increase in QTc interval, utilizing regression analyses to assess the potential influence of various variables. Factors associated with QTc prolongation ≥500 ms included age, body mass index (BMI) <30 kg/m², heart failure, elevated creatinine levels, and documented peak troponin levels (10). Notably, patients with underlying metabolic or cardiological conditions demonstrated a more substantial increase in QTc intervals. The study also found that none of the patients, regardless of the presence of underlying conditions, succumbed to life-threatening arrhythmias during the combination therapy. The results suggest that the azithromycin/HCQ combination does lead to QTc prolongation, with the effect being more pronounced in patients with cardiovascular, renal, and age-related issues.

The data regarding the safety of favipiravir and its effect on the QTc interval in COVID-19-positive patients are contradictory. In a study by Çap et al. (11), although HCQ was shown to prolong the QTc interval, no data were found indicating that favipiravir affects the QTc interval. On the other hand, another study by Sertbaş et al. (12) through a post hoc analysis of a subgroup of patients, reported limited statistical data suggesting that favipiravir may prolong the QTc interval. In our study, since only one patient received favipiravir, it was not possible to make any assessment regarding its effect on the QTc interval. While substantial data suggests that azithromycin prolongs the QTc interval, information on the potential effect of favipiravir on the QTc interval remains limited.

In the present study, none of the schizophrenia patients exhibited QTc prolongation beyond 500 ms during COVID-19 treatment. Unlike previous studies, no heart rhythm problems were observed in patients who were on both antipsychotics and the HCQ/ azithromycin combination. Thus, the concurrent use of antipsychotics with HCQ/azithromycin was found to be safe when accompanied by close electrophysiological monitoring. This may be attributable to the inclusion of only eight patients receiving the azithromycin/HCQ combination in our study. Additionally, one possible reason for the lack of observed differences could be the exclusion criterion in our study, which required patients to be free of underlying cardiological or metabolic conditions. While the azithromycin/HCQ combination does prolong the QTc interval, it is crucial to emphasize the need for comprehensive, multi-dimensional patient evaluation and close monitoring when administering this combination therapy.

In conclusion, schizophrenia patients are particularly vulnerable due to coexisting cardiologic and metabolic comorbidities. In cases of COVID-19 infection, it is essential to consider the potential side effects of drug-drug interactions, underlying metabolic abnormalities, and electrocardiographic effects, especially in mentally ill patients, such as those with schizophrenia or intellectual disabilities(13). The limited number of studies on schizophrenia patients makes the management of COVID-19 infection in this population more challenging at that time. One of the most important lessons to be learned from the COVID-19 pandemic is the need for a detailed evaluation of medications and comorbid diseases, particularly for sensitive groups like those with schizophrenia. This vulnerable group often has numerous comorbid pathologies, both mental and physical(14). While current antipsychotics and those used in the past for the treatment of schizophrenia have many side effects, particular attention should be paid to their tendency to prolong the QTc interval, especially when additional treatment is required.

Limitations

There are several limitations to this study. Firstly, the limited sample size (n=25) reduces the statistical power and effect size of the findings. Additionally, this study was conducted retrospectively, and due to the urgent nature of COVID-19 treatment protocols at the time, a control group could not be established, which constitutes another limitation. Future prospective studies, particularly in the event of a new pandemic, should incorporate a matched control group to facilitate a more robust comparative analysis. Furthermore, due to the absence of a control group, multiple comparisons to assess the specific effects of HCQ on QTc prolongation could not be performed.

Conflict of Interest

There is no conflict of interest between the authors.

Data Availability

All of the data related to the study are recorded in

the hospital's digital system. All of the data has been transferred from this system to an Excel file for study purposes. There is no ethical issue to access our data.

Role of funding source

No funding has been received for this study.

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