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ORIGINAL

Efficacy and Safety of Hydroxychloroquine for the Treatment of COVID-19: An empirical study

Eficacia y seguridad de la hidroxicloroquina para el tratamiento de la COVID-19: un estudio empírico

Vivek Saraswat[1], Pradeepta Sekhar Patro[2], Sourav Rampal[3], Madireddy Sirisha[4], Mukesh Sharma[5], Monika[6]

[1]Centre of Research Impact and Outcome, Chitkara University, Rajpura- 140417, Punjab, India.
[2]Department of Immunology, IMS and SUM Hospital, Siksha 'O' Anusandhan (Deemed to be University), Bhubaneswar, Odisha, India.
[3]Chitkara Centre for Research and Development, Chitkara University, Himachal Pradesh-174103 India.
[4]Centre for Multidisciplinary Research, Anurag University, Hyderabad, Telangana, India.
[5]Department. of Microbiology, Faculty of Medicine and Health Sciences, SGT University, Gurugram, Haryana, India.
[6]Noida Institute of Engineering and Technology Pharmacy Institute, Greater Noida, Uttar Pradesh, India.

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Corresponding author: Vivek Saraswat

ABSTRACT

The new coronavirus disease epidemic of 2019 (COVID-19) has spread worldwide. A quick solution to meet the urgent demand for effective treatment may be drug repurposing. To treat COVID-19, evaluated the clinical effectiveness of hydroxychloroquine and chloroquine. The individuals that received a modest COVID-19 score were randomized to obtain the control therapy or hydroxychloroquine 800 milligrams once daily on Day 7 and 250 milligrams for nine days, except the evaluated the clinical effectiveness of hydrochloride and chlorin equine. Compared to the control group (CtrlGrp) (Group 3), adverse reactions were observed more frequently in those taking chloroquine (Group 1) and hydroxychloroquine (Group 2). The time to clinical recovery (TTCR) was shortened in the Group 1 relation to the CtrlGrp. In the Group 2, there was a tendency toward lower TTCR. Chloroquine and Group 2 reached viral RNA negative substantially faster than the CtrlGrp. The typical instances to become RNA negative in the groups treated with chloroquine, hydroxychloroquine, and controls comprised two days, two weeks, and seven days, correspondingly. Both the length of hospitalization and the results of the lung computed tomography (CT) indicated improvements in the hydroxychloroquine and chloroquine pharmacologic categories. This research provides evidence that hydrochlorothiazide may be used to treat mild COVID-19, and it complements more excellent investigations.

Keywords: COVID-19; Hydroxychloroquine; Chloroquine; Efficacy and Safety; Lung Computed Tomography (CT).

RESUMEN

La nueva epidemia de la enfermedad por coronavirus de 2019 (COVID-19) se ha extendido por todo el mundo. Una solución rápida para satisfacer la urgente demanda de un tratamiento eficaz podría ser la reutilización de fármacos. Para tratar la COVID-19, se evaluó la eficacia clínica de la hidroxicloroquina y la cloroquina. Las personas que obtuvieron una puntuación moderada en la escala COVID-19 fueron asignadas aleatoriamente para recibir el tratamiento de control o hidroxicloroquina 800 miligramos una vez al día durante 7 días y 250 miligramos durante nueve días, excepto en el caso de la evaluación de la eficacia clínica del clorhidrato y la clorina equina. En comparación con el grupo de control (CtrlGrp) (grupo 3), se observaron reacciones

adversas con mayor frecuencia en los que tomaban cloroquina (grupo 1) e hidroxicloroquina (grupo 2). El tiempo de recuperación clínica (TTCR) se acortó en el grupo 1 en relación con el CtrlGrp. En el grupo 2, hubo una tendencia hacia un TTCR más bajo. La cloroquina y el Grupo 2 alcanzaron la negatividad del ARN viral sustancialmente más rápido que el CtrlGrp. Los casos típicos de negatividad del ARN en los grupos tratados con cloroquina, hidroxicloroquina y controles fueron de dos días, dos semanas y siete días, respectivamente. Tanto la duración de la hospitalización como los resultados de la tomografía computarizada (TC) pulmonar indicaron mejoras en las categorías farmacológicas de hidroxicloroquina y cloroquina. Esta investigación proporciona pruebas de que la hidroclorotiazida puede utilizarse para tratar la COVID-19 leve y complementa otras investigaciones más excelentes.

Palabras clave: COVID-19; Hidroxicloroquina; Cloroquina; Eficacia y Seguridad; Tomografía Computarizada (TC) Pulmonar.

INTRODUCTION

The use of hydroxychloroquine (HCQ) has been thoroughly examined about a range of effects in COVID-19 disease, to the point where random selection from the investigation could support nearly any assertion concerning these links.[1] The COVID-19 virus affected around two million individuals globally until the first case in Turkey was identified on March 11, 2020. A group of experts for advice on coronavirus investigation was established by the Turkish Ministry of Health to compile national approvals for the identification, management, and prevention of COVID-19.[2]

An antiviral medication provides convincing evidence of an essential advantage in COVID-19, but the evidence has not precluded any antiviral therapy from having a significant benefit. Before such treatments can be confidently used, more randomized controlled trials involving COVID-19 patients are required.[3] Approximately 47 medications and regiments have been looked into as prospective treatments for COVID-19, and there are additionally multiple ongoing studies and qualitative studies related to COVID-19. Nevertheless, despite all of these studies' initiatives, there is still a lack of an established therapy consensus. Contrarily, the growing body of knowledge regarding the pharmacologic care of COVID-19 patients has resulted in a more considerable disparity in managing COVID patients between institutions in diverse parts of the world.[4]

Based to the European Centre for Disease Control and Prevention, the global COVID-19 disease resulted in 9 400 295 diseased individuals and 482 468 fatalities among December 31, 2019, and June 25, 2020.[5] The United States daily death of 1 000–2 000 during the COVID-19 pandemic produced rises in the Delta and Omicron variants, highlighting the necessity for potent treatments. To treat hospitalized COVID-19 patients, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) for chloroquine (CQ) and hydroxychloroquine early in the pandemic. The drugs were prescribed based on clinical judgment and recommended in certain protocols.[6]

Compared to chloroquine, hydroxychloroquine has a similar clinical safety profile, allowing for a higher daily dosage and, to a lesser extent, less concerns regarding drug-drug interactions.[7] In this treatment of COVID-19, there has been a rise in two malaria medications currently in circulation that belong to the amino-quinoline connecting.[8] This research provides evidence that hydrochlorothiazide may be used to treat mild COVID-19, and it complements more excellent investigations. The goal of was to discover of compounds with possibly antiviral properties against the recently discovered novel SARS-Cove has been motivated by previous outbreaks of several individual coronaviruses associated with a high fatality rate, such as the acute respiratory syndrome coronavirus there is currently no approved COVID-19 medication or prophylactic.[9] The study of describe the COVID-19 patients' hydroxychloroquine pharmacology and indicated concentrations are yet to be characterized, the amount and length of treatment with hydroxychloroquine are currently theoretical, primarily based on laboratory data, and may differ between national guidelines and experiment protocols.[10] Research the quantity of information supporting every treatment regimen in various clinical situations. To determine the efficiency and protection of pharmaceutical COVID-19 treatments that constitutes the foundation of an evidence-based COVID-19 care standard.[11] The goal of COVID-19 individuals with 141 inveterate cases of SARS-CoV-2 infection had been included. Inpatient treatment and death from all causes rates, along with risk-stratified treatment decisions, comprised the primary indicators of outcome.[12] Research assessed the compound and its less damaging derivative, hydroxychloroquine, consisted among the first promising repurpose drugs offered for therapy and prevention. [13] Significant therapeutic benefits for COVID-19 patients using HCQ medicine with or without azithromycin were to be demonstrated by the research.[14] Following the discovery of a new coronavirus in Wuhan, China, in December 2019, traditional Chinese medicine (TCM) took an active role in combating the novel coronavirus pneumonia (NCP) caused by this rapidly spreading virus.[15] Research description treatment effects are currently largely consistent across meta-analyses of observational data and

RCTs examining therapies for covid-19. These results indicate it, despite considering that the assessment is confined to three Covid-19 treatments, information from observational research that has been subjected to meta-analysis may supplement instead of take the place of evidence from RCTs.[16] The goal of for individuals with mild COVID-19, the administration of HCQ+AZT didn't decrease the possibility of hospitalization. The risk of infection and progression is increased by HCQ usage.[17] Research the scenario is controlled and treated individually under the existing system. evaluation of the clinical presentation's severity, the probability of self-isolation, including the potential for disease progression to necessitate hospitalization for treatment constitute all elements in the decision-making process.[18] The goal of determined is generally accepted as the physiological changes involving an individual's immunological and cardiovascular systems during pregnancy make her more susceptible to respiratory consequences of viral infection.[19] Pregnancy-related SARS-CoV and MERS-CoV infections can have fatal consequences, including the need for intubation admissions to the intensive care unit (ICU), renal failure, and even death.

METHOD

Participants

Patients between 18 and 75 had been diagnosed with slight or moderate COVID-19 were eligible. Positive findings for the individuals were discovered from RT-PCR tests on computed tomography (CT) images of the thoracic that looked for lung abnormalities indicative of COVID-19. At admission, oxygen saturation levels in all patients reached above 93 % at room temperature. The thorough description includes detailed inclusion/exclusion criteria. To describe the findings of patients with modest COVID-19 in the following segments. To be classified as having moderate COVID-19, a patient must first complete the diagnostic requirements for the disease, have pneumonia verified by a chest CT scan, and not have severe hypoxia or dyspnea. The objective of the investigation intended to compare the effectiveness, care, and acceptability of Group 1 and Group 2 to the recommended course of treatment.

Inclusion Criteria

- Adults aged 18-50 years
- Diagnosed with mild or moderate COVID-19
- Confirmed positive for SARS-CoV-2 through CT imaging
- Oxygen saturation above 93 % at room air at admission

Exclusion Criteria

- Severe COVID-19
- Pregnancy or breastfeeding
- Known allergy to chloroquine or hydroxychloroquine
- Severe pre-existing medical conditions

Randomization and Masking

This research received various treatments three groups as shown in Table 1. The Chloroquine group (Group 1) received 800 mg of chloroquine phosphate on Day 1, with a regular dosage of 400 mg for the next nine days in addition to routine care. Group 2 was given 250 mg of hydroxychloroquine twice a day for 14 days in addition to their usual medical care. Every CtrlGrp (Group 3) received standard treatment as per local guidelines without adding chloroquine or hydroxychloroquine.

Table 1. Randomization and Treatment Groups

No. of Groups	Treatment	Dosage and Duration
Group 1	Chloroquine phosphate	800 mg on Day 1 and 400 mg every day for the following 7 days
Group 2	Hydroxychloroquine sulphate	250 mg twice daily for 14 days
Group 3	Usual care (standard treatment)	Standard treatment as per local guidelines

Procedures

Daily monitoring was performed to check important signs with temperature, heart rate and blood pressure and clinical recovery signs including symptoms and oxygen saturation. Safety assessments were done to check for adverse events, ECG and cardiac enzymes. Laboratory tests were performed at screening and Day 7, which included chest CT to check lung involvement. Hospitalization days was recorded as days from admission to discharge, and lung CT changes was scored semi-quantitatively to assess lung damage based on affected area.

Daily monitoring included vitals temperature, pulse, BP to assess overall health and treatment response.

Clinical recovery indicators symptom improvement and oxygen to measure treatment and progress. Safety assessments adverse events and ECG to analyse the side effects and cardiac function. Cardiac enzymes to examine cardiac complications. This was all to ensure participant safety and progress as shown in table 2.

Table 2. Procedures and Daily Monitoring

Monitoring Category	Details
Important signs	Temperature, heart rate, blood pressure
Clinical Recovery Indicators	Symptom improvement, oxygen saturation
Safety Assessments	Adverse events, electrocardiogram (ECG), cardiac enzyme levels

Statistical analysis (SA)

The SA uses Kaplan-Meier curves were used to analyse a clinical recovery and time to SARS-CoV-2 RNA negativity. Log-Rank test was used to compare primary outcome between groups, between chloroquine and control, and between hydroxychloroquine and control. The P-value was utilized to establish significance levels, with $p<0,05$ indicating a significant distinction between treatment groups and CtrlGrp for the main outcome.

RESULTS

The table 3 shows the demographics of participants across the three groups. For age, Group 1 had 5 under 30 and 13 30-50, Group 2 had 7 under 30 and 9 30-50, and Group 3 had 4 less than 30 and 10 under the age group 30-50, no significant difference (P=0,618). For gender, Group 1 was 65 % female, Group 2 was 60 %, and Group 3 was 30 % female. Mean BMI was 24,21, 25,35, and 23,35 for Groups 1-3, correspondingly (P=0,444). Pre-existing conditions varied, cardiovascular disease, respiratory illness, and kidney disease were present in all groups. Each group have 20 patients.

Table 3. Demographic characteristics for patients

Characteristic	Group 1	Group 2	Group 3	P-value
Age Group <30	5	7	4	0,618
Age Group 30-50	13	9	10	0,618
Gender				
Female	13 (65 %)	12 (60 %)	6 (30 %)	
Male	7 (35 %)	8 (40 %)	14 (70 %)	
BMI	24,21 ± 2,25	25,35 ± 3,55	23,35 ± 2,63	0,444
Pre-existing Conditions				
None	10 (50 %)	12 (60 %)	8 (40 %)	
Cardiovascular Disease	4 (20 %)	3 (15 %)	6 (30 %)	
Respiratory Illness	3 (15 %)	4 (20 %)	4 (20 %)	
Kidney Disease	3 (15 %)	1 (5 %)	2 (10 %)	

Table 4 presents results in three groups, showing significant differences (p = 0,013) after randomization with CT scores on 7 days. Group 1 had an average CT score of 2,0 (range 0–2,00), Group 2 had a medium of 0,0 (range 0-2,00), and Group 3 had a medium of 2,5 (range 1,50–5,25) in Group 3. Approximately days after randomized for the discontinuation of oxygen treatments, Group 1 had an average of 8,5 days (range 0–9,25), Group 2 had 7,0 days (range 0-9,0), and Group 3 had 8,0 days (range 3,25–14,00), with no significant differences (P = 0,277).

Table 4. Numerical Values of Log Rank Test

Outcome	Group 1	Group 2	Group 3	P-value (Log-Rank Test)
CT Score on after seven days of randomness	2 (0-2,00)	0(0-2,00)	2,5 (1,50-5,25)	0,013
Days from randomized to end of oxygen treatments	8,5 (0-9,25)	7 (0-9,0)	8 (3,25-14,00)	0,277

Figure 1 shows the time to discharge in three groups. The plot shows the cumulative clinical recovery rate over time, which represents the X-axis days and represents Y-axis recovery. The group 1 displays a faster recovery rate compared to both group 2 and group 3, as shown by the first stator slopes in the timeline. Group 2 displays a medium recovery rate, while the group 3 shows the fastest recovery. Statistical analysis, such as,

Kaplan-Meier curves can help determine the differences between the various tests.

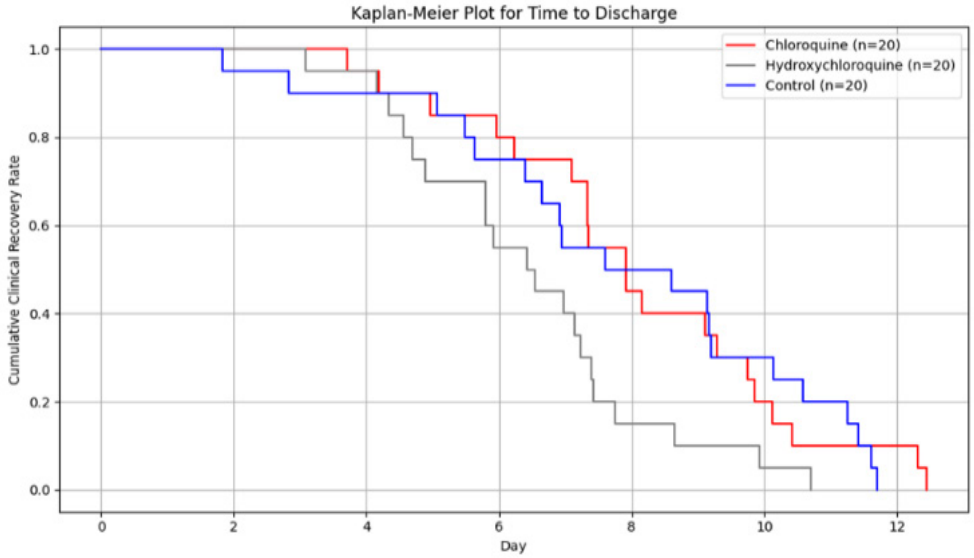

Figure 1. Outcome of Kaplan Meier Analysis

DISCUSSION

Significantly improved by chloroquine phosphate treatment in contrast with the control procedure. Phenobarbital hydrochlorothiazide therapy also reduced hospital stay, expedited the time to viral RNA negative, and enhanced chest CT scan results. At the dosage selected, noticed similar tendencies in the hydroxychloroquine therapy group, but to a lesser extent. In the subgroup receiving hydroxychloroquine medication, it found patterns that appeared moderately strong. Even though the time to discharge for Group 2 and the Group 1 didn't differ substantially, the median length of hospital days was significantly lower.[20]

The investigation generated strong evidence that moderate COVID-19 variations can be treated with chloroquine. However, there are certain limitations to the research, therefore caution must be used when evaluating the data. Given the quick start of the pandemic and the fact that only active medications were available, a double-blind, placebo-controlled study could had been a better option and could greatly reduce the potential impact of open-label use on a specific doctor's opinion.[21]

To improve efficacy while reducing safety concerns, the dosing regimen for chlorine phosphate treatment in the present investigation was developed. The therapy for arthritis caused by rheumatoid arthritis, extraintestinal infection, and malaria has been included on the chloroquine phosphate prescription label in China. The secret to achieving therapeutic success to ensure that blood concentrations are maintained if treating acute viral infections, including COVID-19, it may be necessary to develop novel techniques of chloroquine quickly reach a steady state. Excluded patients having a past of cardiac problems and forbade the usage of drugs that could cause QT elongation or ventricular arrhythmia because therapy with chloroquine may cause cardio toxicity.[22]

Although there was no experimental or clinical evidence at the time regarding hydroxychloroquine's ability to reduce SARS-CoV-2, chloroquine and hydroxychloroquine share a lot of similarities in their chemical composition and mode of action. Considering it has a superior safety record; hydroxychloroquine is more frequently given because it didn't have a firm grasp on the ideal dose protocol that included hydroxychloroquine for exploratory purposes when conducted the trial. Because of safety concerns, the China Food and Drug Administration (FDA) recommended the administered hydroxychloroquine sulfate quantity for rheumatoid arthritis.[23,24]

Each demographic features of the participants in three groups and the conditions already existing pre -existing were largely the same, with no significant differences in age, BMI or gender distribution. Groups are correlated with the presence of pre-existing disorders such kidney, respiratory, and heart diseases. The significant differences in the CT score at day 7 were observed, shown the best results with a group, indicating the potential advantage in reducing lung damage. However, no significant differences were found in the period of oxygen therapy. The recovery rate between groups also varies, with a rapid recovery in a group, suggesting that different treatments may have different effects on clinical consequences. Further statistical analysis is required to confirm these findings.

CONCLUSIONS

The effectiveness of quinine in treating individuals with moderate COVID-19 was investigated. The findings suggest that chloroquine could be useful in treating some types of the illness. When used as prescribed,

hydroxychloroquine has effects that are comparable to those of chloroquine. Nevertheless, the variety of hydroxychloroquine products decreased. Throughout its early phases, the study included several patients with lung symptoms, strong antibodies, but negative viral RNA. To stopped recruiting participants for the study when more individuals were admitted to the ward later on in the clinical investigation. Although the research provides some indication of the therapeutic value of chloroquine, larger studies that seek to determine the optimal dosage schedule are necessary to validate the results.

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CONFLICT OF INTEREST

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AUTHOR CONTRIBUTION

Conceptualization: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh

Sharma, Monika.

Data curation: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Formal analysis: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Research: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Methodology: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Project management: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Resources: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Software: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Supervision: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Validation: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Visualization: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Writing – original draft: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.

Writing – revision and editing: Vivek Saraswat, Pradeepta Sekhar Patro, Sourav Rampal, Madireddy Sirisha, Mukesh Sharma, Monika.