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## Effectiveness of Hydroxy-Chloroquine (HCQ) prophylaxis on COVID-19 positive healthcare workers in tertiary care hospitals, India

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#### Abstract

Chloroquine and hydroxychloroquine were among the first drugs considered for treatment of coronavirus disease 2019 (COVID-19). India has recommended prophylactic use of HCQ among healthcare workers and all other frontline workers as a pre-exposure prophylactic for healthcare workers, particularly for immediate caregivers. The study assesses the effectiveness of Hydroxy-chloroquine (HCQ) prophylaxis among Confirmed Covid-19 positive healthcare workers who have taken the HCQ prophylaxis and who have not taken. A survey approach with an observational research design used in the study. Population for the present study comprises of all, the healthcare workers those are confirmed COVID -19 positive cases of Pan Fortis. The study revealed the effectiveness of the HCQ prophylaxis on the healthcare workers, after high-risk, moderate risk or low risk exposure to COVID-19, HCQ prophylaxis did not prevent illness compatible with COVID-19 when used as pre-exposure prophylaxis. As per the data, who have not taken HCQ prophylaxis also have the same condition as those who have taken. Unlike antiviral drugs, HCQ has no direct effect on COVID-19.

Keywords: COVID 19, Coronavirus, Hydro chloroquine (HCQ), Prophylaxis, Healthcare Workers

## Introduction

Most transmissions of severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2) are thought to occur through respiratory droplets, and the risk of transmission can be reduced by covering coughs and sneezes and maintaining a distance of at least 6 feet from others. When consistent distancing is not possible, face coverings may further reduce the spread of droplets from infectious individuals to others. Frequent hand washing is also effective in reducing the risk of acquisition. In the absence of a vaccine the medical and scientific community is looking intensely at utilizing a pre or post exposure drug that could decrease viremia. The search for a medication that could reduce risk of serious disease, and ideally of any disease and of asymptomatic shedding of SARS-CoV2 is of urgent interest, particularly to decrease the risk to health care workers, first responders, and others with high risk of exposure to patients with COVID-19.

Chloroquine and hydroxychloroquine were among the first drugs considered for treatment of coronavirus disease 2019 (COVID-19). Both have demonstrated in vitro antiviral efficacy against coronaviruses, including SARS-CoV-2. Both have known immune modulating effects in autoimmune diseases that in theory could attenuate the cytokine storm phenomenon. Some researchers have promoted chloroquine and hydroxychloroquine for the treatment and prevention of illness from a variety of microorganisms, including SARS-CoV. Hydroxychloroquine can inhibit replication of SARS-CoV-2 in vitro. Some observational studies have suggested benefits of hydroxychloroquine for the treatment of Covid-19, whereas other treatment reports have described mixed results.

Since late March, 2020 Indian Council of Medical Research (ICMR) 18, which is the apex body of medical research in India, has proposed consumption of HCQ for prophylaxis against COVID-19. In accordance with that guideline, some of the HCWs were voluntarily on preexposure HCQ prophylaxis whereas few others were not. After the outbreak was identified, all those who fulfilled the contact criteria were quarantined and tested for COVID-19 between Day 7-14th of suspected exposure as per Ministry of Health and Family Welfare (MoHFW), Government of India, guidelines.

India has recommended prophylactic use of HCQ among healthcare workers and all other frontline workers. It has also recommended the drug use as a pre-exposure prophylactic for healthcare workers, particularly for immediate caregivers. Whether hydroxychloroquine can prevent symptomatic infection after SARS-CoV-2 exposure is unknown then researcher felt there is further need to check the effectivity of HCQ prophylaxis among healthcare workers who have taken and have not taken the HCQ prophylaxis. Researcher compare the symptomatic and asymptomatic confirmed COVID-19 cases. Hydroxy-chloroquine (HCQ) prophylaxis was given as preventive and/or prophylactic purpose to all tertiary hospitals healthcare workers those are serving COVID-19 positive and suspected patients.

## **Problem statement:**

"A Study to Assess the Effectiveness of Hydroxy-Chloroquine (HCQ) Prophylaxis on COVID-19 Positive Healthcare Workers of Selected Tertiary Care Hospitals, India."

## **Objective of the study**

Hydroxy-chloroquine (HCQ) prophylaxis was given as preventive and/or prophylactic purpose to all tertiary hospitals healthcare workers those are serving COVID-19 positive and suspected patients. The study was carried out to understand the effectiveness of hydroxychloroquine (HCQ) prophylaxis on the health care workers who working directly/indirectly in contact with COVID positive and suspected patients.

## **Hypothesis**

All hypothesis was tested at 0.05 level of significance:

 $H_{01}$  – There is no significant relationship between symptomatic healthcare workers who have taken HCQ prophylaxis and who have not taken HCQ prophylaxis.

## Sample size and methodology

Targeted 620 Fortis healthcare workers those resulted COVID positive in last three months (March to May, 2020). We received 510 (82%) responses. Out of this, 421 responses validated for the study. 89 responses excluded due to incomplete information. A survey approach with an observational research design used in the study. Population for the present study comprises of all, the healthcare workers those are confirmed COVID -19 positive cases of Pan Fortis. Purposive sampling was carried out in the study. A structured questionnaire with 17 questions to obtain the demographic characteristics and clinical aspects of healthcare workers.

The information was filled in the Microsoft form by the survey individuals itself. Those who could not access due to language barrier such as housekeeping and GDA were assisted by their educator or infection control nurses in their respective Fortis Hospital. The survey was initiated in 14 tertiary Hospitals. Each Participants took average 3-4 minutes to fill the form. The data collection exercise was initiated from 1<sup>st</sup> July to 6<sup>th</sup> July, 2020.

## **Inclusion criteria:**

- Healthcare workers who have confirmed cases of COVID-19 and completed the questionnaire.
- All the symptomatic and asymptomatic healthcare workers

## **Exclusion criteria:**

- Healthcare Workers who didn't complete the survey
- Healthcare workers taking care of COVID cases but themselves not confirmed positive cases

## **Content validity of tool:**

The constructed tool along with the objectives, blue print & criteria checklist was sent to 3 experts.

For structured questionnaires the item level content validity index (CVI's) was ranged from 0.8 to 1, the scale level content validity index using the averaging was 0.90. In order to assess the reliability of questionnaires, was assessed using test-retest method (r = 0.78) and tool was found reliable.

## **Results of the study**

# **Results of the present study organized under following sections:**

Descriptive and inferential statistics were used to analysis the data on the basis of objectives.

## 1. Demographic details of respondents

Demographic characteristics revealed that 54% were male and 46% were females participated in the study. Among them majority of the respondents (55%) were belongs between 18-30 years of age group, followed by the age group 30-45 years i.e.; 40%. Very few (5%) were between age group of 45-60 years & only 1% were aged more than 60 years.

## 2. Key findings

a). Healthcare workers in the service of direct care for COVID 19 positive patients:



## Figure 1: Pie Chart of the healthcare workers involved in the service of direct care for COVID patients

Figure 1 shows that out of 421 respondents, 198 (47%) respondents were involved in the direct care for COVID -19 positive patients. Among them, majority of the respondents (82%) were general duty assistant (GDA), Half of the respondents (57%) were doctors whereas (53%)

were nurses. Rest of the respondents were technician (25%), F&B (25%), administration (17%), finance (14%) and others were (15%) who were directly involved in the service for COVID -19 positive patients.

#### b) Distance maintained from the COVID- 19 Positive Patients while working in the department:



## *Figure 2:* Bar Chart of healthcare workers who have maintained distance from COVID patient while working in the department

Figure 2 shows that out of 421 respondents, majority of the respondents 60% were maintained distance more than one meter while on the other hand only 19% have maintained less than one meter and 21% were not responded.

Among 82 (19%) respondents have maintained distance less than one meter, it was found that majority of the respondents were symptomatic (84%) and few were asymptomatic (16%) cases.

If we look into the category of the respondents who have maintained less than one-meter distance from COVID-19 positive patients, more than half were nurses (57%), whereas only 15% were doctors, 12% were technicians, only 4% were housekeeping and 4% were GDA and 1% were from food and beverages department.

### c) HCQ prophylaxis – Taken and/or have not taken by the respondents:



#### Figure 3: Pie chart showing the percentage of healthcare workers who have taken HCHQ prophylaxis

Figure 3 shows that out of 421 respondents, only 39% were taken HCHQ prophylaxis whereas majority 61% were not taken the HCHQ prophylaxis.

55% were males and 45% were females who have taken the HCQ prophylaxis and 255 (61%) respondents have not taken the HCQ prophylaxis, 53% were males and 47% were females respondents.

Out of 421 respondents, 166 (39%) respondents have taken the HCQ prophylaxis, among them



*Figure 4:* Bar chart showing the percentage of healthcare workers Asymptomatic and Symptomatic who have taken HCHQ prophylaxis and have not taken

Researcher compares the condition of the respondents at the time of diagnosed COVID-19, 89.16% were symptomatic who have taken the prophylaxis and on the other hand 89.4% were also symptomatic who have not taken the HCQ prophylaxis. But 10.84% were asymptomatic who have taken HCQ prophylaxis and 10.59% were also asymptomatic who have not taken the HCQ prophylaxis.

The comparison of the respondents' status after diagnosed COVID-19, out of 421 respondent's majority of respondents (61%) were taken HCQ and (65%) have not taken the HCQ prophylaxis, both the group were home quarantine. Whereas (28%) have taken and (27%) have not taken, both were admitted in the hospital. Those who have taken (10%) and (8%) who have not taken were hospital quarantine.

Respondents who have taken HCQ prophylaxis, out of 166 respondents among them, (50%) have completed their course of treatment where 21% also have completed but followed it for 3 weeks only, 23% of the respondents have left the course in between, they were experiencing severe side effects like GI disturbances, sever vomiting, diarrhea, nausea, rashes, itching, loss of appetite, syncope, chest heaviness, headache. 4% of the respondents have left due to some other reasons such as a. after tested positive started HCQ for 5days, b. started post admission in the hospital, c. has not received further.

Respondents who have not taken HCQ prophylaxis, out of 255 respondents, 33% of the respondents felt HCQ not required, 24% of the respondents concerned over the consequences with side effects by the others like gastric disturbances, fainting and/or syncope, loss of appetite and many more assumptions. 11% not responded, 2% have some other reasons i.e.: a. age is more than 60 years and having cardiac risk, b. breast feeding mother, c. illness after HCQ taken it (felt chest heaviness, headache) and no guidance for taking HCQ by medical team.

Table 1. shows mean and 'r' value of symptomatic cases who have taken and have not taken the HCQ prophylaxis

HCQ Prophylaxis	Mean	R Value
Symptomatic have taken	24.667	0.875
Symptomatic have not taken	46.333	(p <0.0001)



*Figure 5:* Scattered plot diagram showing linear relationship between the symptomatic cases of HCQ prophylaxis taken and have not taken

Table 1. shows that the computed value of correlation coefficient (r = 0.875) (p < 0.0001)\*\* at 0.05 level of significance, hence it inferred that there is a strong positive correlation (linear relationship) between symptomatic cases who have taken the HCQ and who have not taken the HCQ prophylaxis. Hence, it means both the cases have no effectivity of HCQ prophylaxis, so research hypothesis is accepted and null hypothesis is not accepted.

## Discussion

The findings of this study revealed that respondents who have taken HCQ prophylaxis had symptoms like- abdominal discomfort, vomiting, diarrhea and even who have not taken also had symptoms like nausea, abdominal discomfort, loose stools. No difference found between both the cases, among them around 28% of the respondents who were symptomatic were admitted in the hospital. Whereas those have not taken 27% were admitted and symptomatic which shows that there is no significance of HCQ prophylaxis on any of the respondents. A randomized trial, on 107 participants had a primary outcome of symptomatic illness, with SARS-CoV-2 infection confirmed by molecular test or by the development of a compatible, COVID-19-related syndrome based on CDC criteria. Due to limited access to molecular diagnostic testing, confirmation of infection occurred for only 16 of the 107 participants (15%). There was no statistically significant difference between the incidences of a primary outcome in the hydroxychloroquine and placebo groups (11.8% vs. 14.3%, respectively; P = 0.35). There were more adverse events in the hydroxychloroquine group; mostly nausea, loose stools, and abdominal discomfort, with no serious adverse reactions or cardiac arrhythmias.

India's health ministry advisory says: "The data on assessment of HCQ prophylaxis among 1,323 HCWs indicated mild adverse effects such as nausea (8.9%), abdominal pain (7.3%), vomiting (1.5%), hypoglycemia (1.7%) and cardio-vascular effects (1.9%).Pearson correlation coefficient was used to determine the relationship between symptomatic respondents who have taken HCQ prophylaxis and who have not taken the HCQ prophylaxis, it was found that there is a strong positive relationship, which shows that HCQ prophylaxis is ineffective and both the cases were having same symptoms and admitted in the hospital.

## Conclusion

This study revealed the effectiveness of the HCQ prophylaxis on the healthcare workers, after highrisk, moderate risk or low risk exposure to COVID-19, HCQ prophylaxis did not prevent illness compatible with COVID-19 when used as pre-exposure prophylaxis. As per the data, those have not taken HCQ prophylaxis also have the same condition as those who have taken. Unlike antiviral drugs, HCQ has no direct effect on COVID-19. Its use against COVID-19, even as a prophylaxis, has to be continuously monitored.

## Limitations

Randomization was not done due to insufficient number of cases to drawn a conclusion on an efficacy of HCQ prophylaxis, in terms of prevention and/or prophylaxis measures for COVID-19.

## Recommendations

The study can be cast off as a review to conduct the randomized control trials to find the efficacy of HCQ prophylaxis.

## **Ethical consideration**

Ethical permission prior to conduction the data collection was obtained, privacy and confidentiality of the respondents was maintained throughout the study.

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*Study initiated & conceptualized:* Sandhya Shankar Pandey

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