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## Hydroxychloroquine for 2019 Novel Coronavirus (COVID-19)



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### ABSTRACT

Novel Corona-infection disease 2019 (COVID 19) is caused by a unique harmful coronavirus and prompts possibly deadly destructive pneumonia and heavy respiratory misery condition. It was at first pronounced as a general well-being crisis of universal worry by WHO followed by pandemic on 12<sup>th</sup> March 2020. The antiviral activity of hydroxychloroquine has been a focal point to various scientists because of its properties. The goal of this article is to explain the safety & efficacy of HCQ and the advantages and disadvantages of utilizing this medication on coronavirus. Data were collected from various databases: ELSEVIER, WebMD, ClinicalTrials.gov, World Health Organization international clinical trials, and international journals were searched until May 2020. Hydroxychloroquine (HCQ) is an anti-malarial drug that's being tested as a prophylactic treatment to forestall COVID-19 infection worldwide. According to the foundations laid by the ICMR on the prophylactic use of hydroxychloroquine on 23<sup>rd</sup> March 2020, the drug was tested within the laboratories and showed promising ends up in treating and preventing COVID-19 infection. However, a recent study published within the lancet showed that giving hydroxychloroquine to people infected with COVID-19 infection can increase their risk of death due to its unknown side effects & adverse effects said by the executive group of the solidarity trial (international clinical trial launched by the WHO). The speed and volume of clinical trials launched to research potential therapies for COVID-19 highlight both the requirement and capability to supply high-quality evidence even amidst of a virulent disease.



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## INTRODUCTION

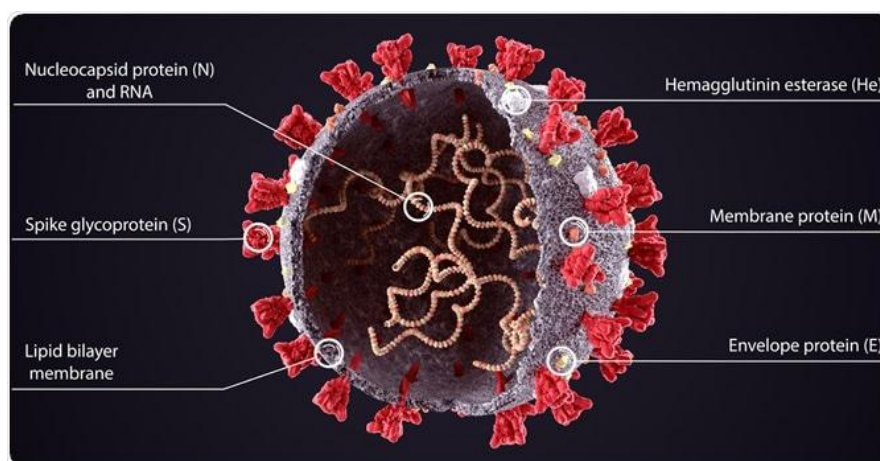
In December 2019, an epidemic of pneumonia because of unknown cause occurred in Wuhan, Hubei province, China with clinical presentations greatly resembling virus infection and rapidly spread throughout the country within 1 month <sup>[7]</sup>. The pathogen of this disease was confirmed as a unique coronavirus by molecular methods and was initially named as 2019 novel coronavirus (2019-nCoV) <sup>[2]</sup>; however, WHO announced a new name on February 11<sup>th</sup>, 2020, for the epidemic disease: Coronavirus disease (COVID-19) <sup>[5]</sup>. COVID-19 (Coronavirus disease-2019), a disease caused by the coronavirus SARS-CoV-2 (Severe acute respiratory syndrome- coronavirus-2), has emerged as a rapidly spreading disease affecting over 200 countries across the world at the present <sup>[4]</sup>. The disease is primarily spread through large respiratory droplets, though the chance of other routes of transmission can't be ruled out, because the virus has been found in stool and urine of affected individuals <sup>[3]</sup>. On 11<sup>th</sup> March 2020, WHO declared this disease as pandemic <sup>[1]</sup>.

At the time of scripting, this article, coronavirus cases: 6,982,964 cases with 402,273 deaths & 3,413,441 recovered spanning over 213 countries and territories and a couple of international conveyance are reported <sup>[6]</sup>. This might be an underestimate due to the lower number of diagnostic tests and case identification partly because of poor health services in most countries. The mortality rate stands at 0.28% <sup>[8]</sup>.

Diversion of all healthcare facilities toward the COVID-19 pandemic is probably going to extend the morbidity and mortality due to other health problems <sup>[9]</sup>. Another conundrum faced could be a high secondary infection rate among high-risk healthcare workers annexing the already burdened healthcare system <sup>[10]</sup>. This is able to not only compound the approaching shortage of healthcare facilities but would also mean more pervasive spread. Prevention is thus the foremost effective strategy to not only prevent more spread and deaths but also to unburden the healthcare system. However, there are challenges involved. Although methods like mitigation, quarantine, isolation, social distancing are being employed and these don't seem to be infallible. Contact tracing for the spread of infection from asymptomatic or mild undiagnosed cases, transition to community spread, and factors like uncertainty regarding the survival of the virus in air or fomites are cumulatively adding to the mammoth task <sup>[11]</sup>. Hence, the main focus has now been shifted toward evaluating and implementing other strategies like chemoprophylaxis and vaccination besides the continued use of the barrier system <sup>[12]</sup>. Vaccine development will take time, between 12-18 months, as

human trials are underway. There is a lot of speculation on chemoprophylaxis stemming from the available data on the use of some antimalarial drug, HCQ, which have been tried for the treatment of this disease [9]. The incubation period of the virus is the time between the exposure and the display of symptoms. Current data recommends that the brooding period ranges from 1 to 12.5 days (with middle appraisals of 5 to 6 days), yet can be up to 14 days [13].

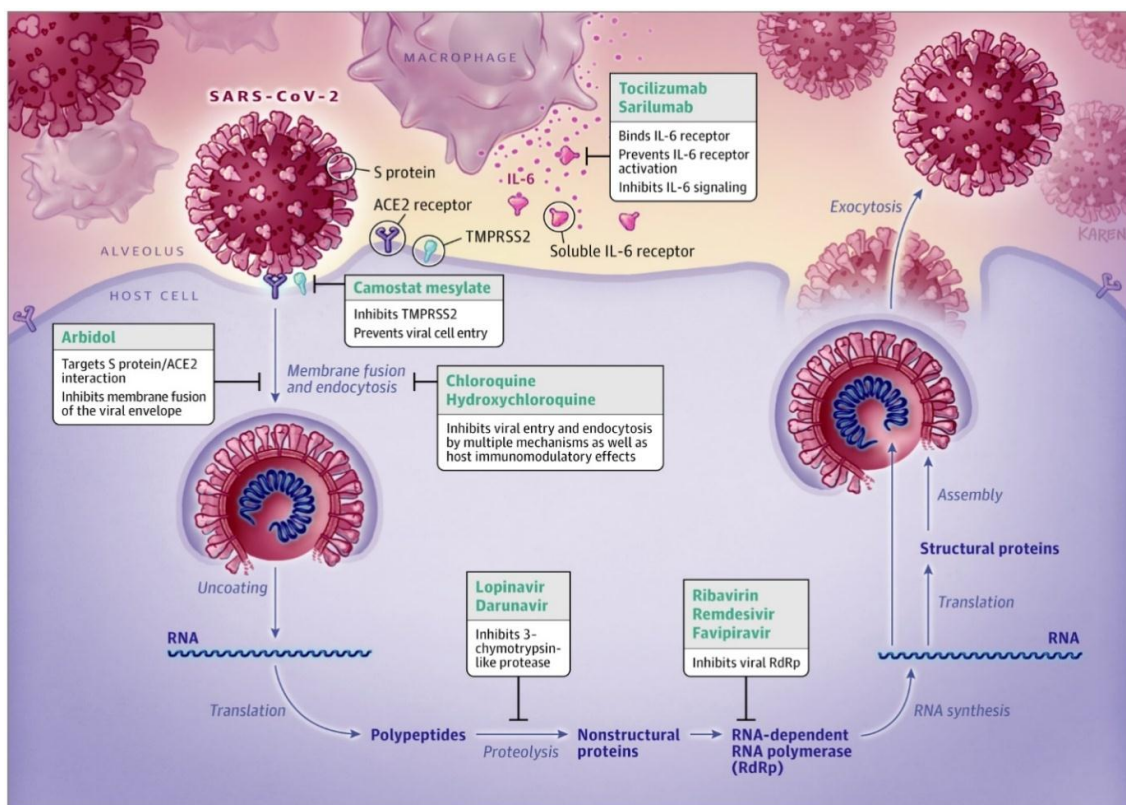
At present, there's no vaccine or antiviral treatment for human and animal coronavirus (COVID-19), due to its key role within the virus cell receptor interaction, the surface structure of spike glycoprotein(s) (**Figure 1**) is especially important for the event of antivirals [14].



**Figure No. 1: Structure of COVID-19**

HCQ is a medication that has been used for a long time. It's most commonly used in the treatment and prophylaxis of malaria. However, these antimalarial drugs are known also to possess anti-inflammatory and antiviral effects and are used for several chronic diseases like systemic lupus erythematosus with low adverse effects. The antiviral action of HCQ has been a degree of interest to different researchers because of its mechanism of action. Several *in vitro* studies have proven their effectiveness on severe acute respiratory syndrome virus and currently, both *in vitro* and *in vivo* studies are conducted on 2019 novel coronavirus (COVID - 19). Hydroxychloroquine is comparatively a secure drug. Commonest side effects include gastrointestinal symptoms, pruritus and dermatological changes that may be occurred in up to 10% of the patients. The foremost severe side effects have low incidence. They include neuromyopathy of proximal muscles, cardiotoxicity and irreversible retinopathy [15]. The mechanism of action of HCQ is that it primarily inhibits the entry, transport and post-entry

stages of SARS-CoV-2. It increases endosomal pH & interferes with the glycosylation of cellular receptor of SARS-CoV & thereby it has the potential to block viral infection. It also inhibits cathepsins, that lead to the formation of the autophagosome which cleaves SARS-CoV-2 spike protein (**Figure 2**). It has similar molecular structure like chloroquine except for an additional hydroxy moiety in one terminal. HCQ [EC 50 =0.72  $\mu$ M] was seen as increasingly powerful than chloroquine [EC 50 =5.47 $\mu$ M] against SARS-CoV-2 in *in-vitro*. The efficacy of HCQ is not yet proven in animal model in *in-vivo* study [16]. Currently, there is no evidence from RANDOMIZED CLINICAL TRIALS that any potential therapy improves outcomes in patients with either suspected or confirmed COVID-19. There are no clinical trial data supporting any prophylactic therapy. More than 300 active clinical treatment trials are underway. This review summarizes current evidence regarding HCQ, for COVID-19 and provides a summary of current clinical experience and treatment guidance for this novel epidemic coronavirus [17].



**Figure No. 2: COVID-19 Viral Cycle & Potential Drug Targets**

## MATERIALS AND METHODS

The goal of this article is to explain the safety & efficacy of HCQ and the advantages and disadvantages of utilizing this medication on Coronavirus. Data were collected from various databases: PubMed, ELSEVIER, WebMD, ClinicalTrials.gov, WHO International clinical trials, and other Review articles & International journals were searched till May 2020. The search terms used in various combinations were: “chloroquine”, “HCQ”, “coronavirus”, “coronavirus disease”, “coronavirus disease-19”, “COVID-19”, “severe acute respiratory syndrome”, “SARS-CoV-2”, “prophylaxis”, and “preventive”.

## RESULTS AND DISCUSSION

The Indian council of medical research last week expanded the use of HCQ as a prophylaxis for frontline COVID-19 workers <sup>[15]</sup>. The worldwide effects of the SARS-CoV-2 pandemic has been unparalleled and it has prompted the scientific community to consider all possible solutions. Due to COVID-19 similarities to SARS-CoV, several researchers have proposed the use of hydroxychloroquine on the novel virus. Since the structure and mechanism of action of HCQ is similar to chloroquine except an additional hydroxy moiety in one terminal in HCQ, which act as a weak base that can change the pH of acidic intracellular organelles including endosomes/lysosomes, essential for the membrane fusion. It is believed that both the agents could be effective tools against SARS-CoV-1 and SARSCoV-2 <sup>[18]</sup>.

**Geleris J et al.** tested 1446 consecutive patients, 70 patients were intubated, died, or discharged inside 24 hours after introduction and were barred from the investigation. Of the remaining 1376 patients, during a median follow-up of 22.5 days, 811 (58.9%) received HCQ (600 mg twice on day 1, then 400 mg day by day for a middle of 5 days); 45.8% of the patients were treated in 24 hours after introduction to the crisis division, and 85.9% in 48 hours. HCQ treated patients were more seriously sick at baseline than the individuals who didn't get HCQ. In general, 346 patients (25.1%) had an essential end-point occasion (180 patients were intubated, of whom 66 accordingly kicked the bucket, and 166 passed on without intubation). Although many drugs have *in-vitro* activity against the virus, the proposal that such drugs might provide more benefit than harm is inappropriate in the face of no clinical evidence supporting efficacy and safety in patients with COVID-19. International multicenter studies, such as the discovery study (NCT04315948) and the solidarity study



(EudraCT Number 2020-000982-18), will randomize patients with COVID-19 to receive different antiviral drugs, including HCQ, in adaptive study design [19, 20].

HCQ is an anti-malarial drug that's being tested as a prophylactic treatment to forestall COVID-19 infection worldwide. According to the foundations laid by the ICMR on the prophylactic use of HCQ on 23<sup>rd</sup> March 2020, the drug was tested within the laboratories and showed promising ends up in treating and preventing COVID-19 infection [21]. In light of recent publications of evidence on the safety and efficacy of HCQ as a therapy for COVID-19 patients, the executive group of the solidarity trial (international clinical trial launched by the WHO) decided to implement a transitory respite of the HCQ arm in the investigation as insurance while the wellbeing information is being surveyed. As an example, an observational study published in the Lancet on 23<sup>rd</sup> May 2020 found that, among 1,00,000 patients from multiple countries randomized to get HCQ, when utilized alone or with a macrolide, there was a higher death rate and an increased frequency of irregular heartbeats [22]. **Mustafa, Nasir**, stated that chloroquine/ HCQ has strong antiviral effects on SARS-CoV infection of primate cells. Chloroquine/ HCQ has been shown to be capable of inhibiting the *in vitro* replication of several coronaviruses. Recent publications support the hypothesis that chloroquine/ HCQ can enhance the clinical result of patients contaminated by SARS-CoV-2 [23].

**Yao et al.** also tested the effect of HCQ and chloroquine *in vitro*. They divided the experiment into two phases: treatment study and prophylaxis study. In the treatment study, the EC<sub>50</sub> values for chloroquine were 23.90 and 5.47 $\mu$ M at 24 and 48 hours, respectively, and the EC<sub>50</sub> values for HCQ were 6.14 and 0.72 $\mu$ M at 24 and 48 hours, respectively. In the prophylaxis study, the EC<sub>50</sub> esteems for CQ were >100 and 18.01 $\mu$ M at 24 and 48 hours, respectively, and the EC<sub>50</sub> esteems for HCQ were 6.25 and 5.85 $\mu$ M at 24 and 48 hours, respectively. They concluded that HCQ is more successful *in vitro* than chloroquine for both prophylaxis and therapy. **Gautret et al.** medicated 20 patients with HCQ and contrasted the outcomes and 16 controls in France. They used PCR to measure the viral load on day 3, 4, 5 and 6 of post inclusion. The treatment group had a higher age mean, but no difference in gender was made between the two groups. Asymptomatic patients and patients with both lower and upper respiratory tract infections were treated. They inferred that HCQ was compelling in viral burden decrease. The results on day 3 indicated that 50% of the hydroxychloroquine-treated patients had a viral burden decrease with a  $p = 0.005$ ; on day 4, it

indicated a 60% decrease with a  $p = 0.04$ ; on day 5, a 65% decrease with a  $p = 0.006$ ; and on day 6, 70% of the patients demonstrated viral burden decrease with a  $p = 0.001$ . Furthermore, they described the synergistic effect of azithromycin when using it alongside HCQ in decreasing the viral load. The dual treatment showed 100% decrease on the viral load with a  $p < 0.001$  by day 6, while hydroxychloroquine alone showed a 70% decrease [24-26].

During the investigation time frame, 10,698 deaths were disclosed. The demise rate was to be 9.3% in the people who got a placebo. However, it was found to be increased in people who got the medication. The study showed that the death rate was 18% in people who got HCQ, 23.8% in the ones who got HCQ with antibiotics, 16.4% in the group who got chloroquine and 22.2% in those who got chloroquine with the antibiotic. The study further found that the group who got the drug showed an increased risk of getting irregular heartbeats (arrhythmias). When compared to the group that got a placebo, 6.1% increased risk of arrhythmias were seen in HCQ, 8.1% in HCQ with the antibiotic, 4.3% in chloroquine and 6.5% chloroquine with the antibiotic. To conclude, the study suggests that HCQ should not be used against COVID-19 outside of clinical trials at this point (**Figure 3**) [27]. The Data safety and Monitoring committee will keep on screening the wellbeing of all therapeutics being tested in the solidarity trial [28]. Multiple institutions worldwide are already using hydroxychloroquine in their treatment guidelines, including the Centers for Disease Control and Prevention (CDC), pointing to the relevance of this drug in the current pandemic [29].

## CONCLUSION

HCQ has shown several antiviral mechanisms, including the inhibition of inflammatory cytokines such as IL-1, IL-6 and TNF-alpha. The impact of hydroxychloroquine on SARS-CoV-2 (COVID-19) has been studied *in-vitro*, exhibiting its pre-section result, likely because of the hindrance of the SARS ACE2 receptor and the viral restraint post-passage. Also, *in-vivo* studies have demonstrated clinical improvement and decrease in the viral load. Several double-blinded, randomized, placebo-controlled clinical trials are being conducted to further investigate the effects of HCQ on COVID-19. There are currently over 20 trials of HCQ underway in India. Recent advice issued by a national body from a South-Asian country suggested the use of prophylactic HCQ at a dose of 400 mg twice daily, followed by once weekly, for healthcare workers managing patients with COVID-19 and close contacts of proven COVID-19 cases. World Health Organization said that the drug remains safe for treatment of rheumatoid arthritis and malaria. In clinical practice HCQ is normally endorsed

in a day by day portion of 200mg to 400mg for treatment of infections, for example, rheumatoid arthritis and systemic lupus erythematosus for extended treatment periods with great forbearance. With available evidence for its safety and beneficial effect as a prophylactic drug against SARS-COV-2 during the earlier recommended 8 weeks period, the specialists further suggested for its utilization past about two months on week after week measurements with severe checking of clinical and ECG boundaries which would also ensure that the therapy is given under supervision. On 23<sup>rd</sup> May 2020, the executive group of the solidarity trial chose to actualize a brief interruption of the HCQ arm of the trial, in light of concerns raised about the security of the medication.

**While several drug trials are ongoing, there is currently no proof that hydroxychloroquine or any other drug can cure or prevent COVID-19.**

The misuse of hydroxychloroquine can cause serious side effects and illness and even lead to death.

WHO is coordinating efforts to develop and evaluate medicines to treat COVID-19.

**FACT: There are currently no drugs licensed for the treatment or prevention of COVID-19**

World Health Organization #Coronavirus #COVID19 27 April 2020

**Figure No. 3: MythBuster on HCQ**

On 3<sup>rd</sup> June 2020, on the basis of the available mortality data, the members of the committee have prescribed that there are no motivations to adjust the trial convention. The executive group got this suggestion and supported the continuation of all arms of the solidarity trial, including hydroxychloroquine.

In general, there are no specific antiviral drugs or vaccines for 2019-nCoV. All of the drug options originate for a fact medicating SARS, MERS, or some other new flu infection already. Effective indicative help stays key to treatment. These drugs above would be helpful and the efficacy needs to be further confirmed.



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