SJIF Impact Factor: 5.464

WORLD JOURNAL OF ADVANCE HEALTHCARE RESEARCH

ISSN: 2457-0400
Volume: 5.
Issue: 5.
Page N. 151-152
Year: 2021

Review Article www.wjahr.com

WHY USFDA APPROVED HYDROXYCHLOROQUINE?

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Received date: 23 July 2021 **Revised date:** 13 August 2021 **Accepted date:** 03 September 2021

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ABSTRACT

In the current scenario there is a severe outbreak of Coronavirus disease 2019 (COVID 2019). This outbreak started from China in December 2019.From there this infectious disease outbreaks worldwide up to April 9, 2020.The World Health Organization declares this as a worldwide pandemic. The current news shows how the infection spreads over USA, Italy and Spain, India and more than ninety countries of the world. Recently on March 28,2020 US FDA approves Hydroxychloroquine and Chloroquine for the treatment of COVID 19. There are few invitro reports are available with these antimalarial drugs that confirms the use for treatment of COVID 2019, but no evidence of clinical trials. The current viewpoint trying to explain both the situation that why these antimalarial drugs can be used for treatment and why the exclusive use should be prohibited.

INTRODUCTION

On the March 28,2020 RADM Denise M. Hinton Chief Scientist Food and Drug Administration of USA had issued Emergency Use Authorization (EUA) for the use of Chloroquine phosphate and Hydroxychloroquine sulphate for treatment of COVID-2019, by giving response letter to Dr. Rick Bright, Ph.D., The Director, Biomedical Advanced Research and development authority(BARDA),office of assistant secretary for preparedness and Response(ASPR) U.S., Department of Health and Human Services(HHS).This issuance of both the drugs was on the basis of in-vitro study and some anecdotal clinical data. On the basis of this data available these drugs are recommended in several countries for the treatment of COVID-19 disease. This recommendation of Chloroquine phosphate and Hydroxychloroquine sulphate was based on no clinical trials available for treatment of COVID-19[1]

The drugs Chloroquine phosphate and Hydroxychloroquine sulphate which are antimalarial activity are also used in the treatment of rheumatoid arthritis (RA), systemic lupus erythematosus (SLE) and other inflammatory rheumatic diseases. [2]

The Chloroquine phosphate has recently reported with potential broad-spectrum antiviral drug which was previously used as anti-malarial and autoimmune disease drug. It blocks the virous infection by increasing endosomal pH required for virus or cell fusion. It also interferes the glycosylation of cellular receptors of SARS-CoV. It functions by both entry and post entry stages of COVID-19 infection in Vero E6 cells. The chloroquine also shows immune-modulating activity which may responsible for enhancing antiviral activity in vivo.[3]

The Hydroxychloroquine sulphate is the derivative of chloroquine phosphate is proved more effective than chloroquine to inhibit SARS-CoV-2 invitro. This study was carried out by taking physiologically-based pharmacokinetic models. (PBPK) Based on this PBPK models, the Hydroxychloroquine loading dose of 400 mg twice daily of Hydroxychloroquine sulphate sulfate given orally, followed by maintenance does of 200 mg given twice daily for four days is recommended for SARS-CoV-2 infection. This dosage are three times potent than that of chloroquine phosphate.[4]

The Hydroxychloroquine sulphate which is derivative of chloroquine phosphate was synthesized in 1946.The hydroxyl group was introduced in to the chloroquine which shows 40% toxic than chloroquine phosphate in animals. For the treatment of systematic lupus erythematosus and rheumatoid arthritis Hydroxychloroquine sulphate is widely used as these are

autoimmune diseases. In Chinese clinical trial registry seven clinical trial registries were found on February 23, 2020 for the use of Hydroxychloroquine sulphate for the treatment of COVID-19. But there is no evidence that it is more potent over chloroquine up to February 23, 2020.The Hydroxychloroquine sulphate is also acting as an anti-inflammatory agent which decreases the production of cytokines in pro-inflammatory factors. Therefore, it can be efficiently inhibiting the SARS-CoV-2 infection in vitro.[5]

The ventricular arrythmias, QT prolongation and other cardiac toxicity are some adverse effects of antimalarial drugs and there may the chances of risk in case of critically ill patients. In current pandemic scenario it is the duty of physicians and researchers they should properly clarify the patients to whom the antimalarial medications are helpful in COVID-19. This is necessary because up to the 31 march 2020 there are almost 10 randomized trials are going on and the results may appear in coming weeks. The physicians firstly educate themselves for treating COVID-19 by using Chloroquine phosphate and Hydroxychloroquine sulphate. The physicians should avoid the use which may called as misuse of Chloroquine phosphate and Hydroxychloroquine sulphate for prophylaxis of COVID-19.[6]

CONCLUSION

The above discussion suits the title of the paper that why USFDA approved Hydroxychloroquine sulphate? Because the answer finding gives both the opinions. There are certain findings on the basis of invitro studies that these drugs can be used for COVID-19. But there are no clinical trials are available for this claim. Some study explains that Hydroxychloroquine sulphate is more potent over chloroquine phosphate for the treatment of COVID-19. But the certain finding are shows that these antimalarial drugs having certain adverse effect and no events are available for the use of these drugs for prophylaxis purpose. In conclusion it may say that there is overlapping situation whether to use Chloroquine phosphate and Hydroxychloroquine sulphate for the treatment of COVID-19.

ACKNOWLEDGEMENT

The author is thankful to Dr. M.J. Chavan, Principal and Management of Amrutvahini College of Pharmacy, Sangamner, M.S., India.

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