

## CLINICAL CHARACTERISTICS AND OUTCOME OF PATIENTS WITH CORONA VIRUS INFECTIONS

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Received : 22/10/2023  
Received in revised form : 05/12/2023  
Accepted : 22/12/2023

**Keywords:**  
Adverse effect, COVID 19, drugs.

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DOI: 10.47009/jamp.2023.5.6.264

Source of Support: Nil,  
Conflict of Interest: None declared

*Int J Acad Med Pharm*  
2023; 5 (6); 1291-1294



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### Abstract

**Background:** The purpose of this study is to find out the adverse effect of several medications that are administered for the treatment of patients who have mild, moderate and severe case. **Materials and Methods:** In study carried out a retrospective, cross-sectional, observational and descriptive study. Patients diagnosed with COVID-19 ranging from mild, moderate and severe were given as part of this treatment. The primary objectives are to find out the adverse effect of several medications that are administered for the treatment of patients who have mild to severe case. **Result:** A total of 524 patients included in this study mild to severe COVID 19 infection led to adverse events were related to gastrointestinal system and CNS. **Conclusion:** In this study, safety of various drug combinations in the treatment of COVID-19 was evaluated. Overall no major safety concerns were noted with various drug combinations. Most common adverse events were related to gastrointestinal system but there incidence was very minimal.

## INTRODUCTION

COVID-19 is an infectious disease caused by SARS-CoV-2, a coronavirus discovered in December 2019 that caused a worldwide pandemic. The disease is primarily transmitted through inhaled drops when coughing, sneezing, or conversing with sick people.<sup>[1-4]</sup> Furthermore, infection can arise as a result of contact with a contaminated surface.<sup>[4-6]</sup> SARS-CoV-2 is a positive, single-stranded RNA virus (30 KB in length) with a nucleocapsid that enters infected cells via endocytosis or membrane fusion and can cause respiratory and intestinal illnesses, liver and neurological damage in humans and some animals.<sup>[7]</sup> SARS-CoV-2 comprises spike (S) glycoproteins, which are made up of two functional subunits: S1, which binds to the host cell receptor, and S2, which fuses viral and cell membranes.<sup>[3]</sup> ACE2 is a functional receptor for SARS-CoV-2 entrance into cells,<sup>[8-10]</sup> and ACE2 expression is high in the lung, heart, ileum, kidney, and bladder.<sup>[11]</sup> Although a lot of work has gone into developing a vaccine thus far, there is currently only one COVID-19 vaccine or treatment, and elderly people who have underlying medical conditions are more vulnerable to serious

illness.<sup>[12]</sup> Therefore, knowing how to strengthen their immune system to fend off SARS-CoV-2 infection or manage the severity of disease progression is crucial information for the majority of people. Every day, a great deal of research is conducted worldwide in an effort to discover a medication that is both successful and shows promise in treating, managing, or preventing COVID-19. Certain medications have been reported to be effective in treating COVID-19. Here, we attempt to look into a few of them, such as Ceftriaxone, Remdesivir remdesivir, hydroxychloroquine, azithromycin, Doxycyclin, Ivermectin, Atorvastatin etc. In this study several adverse effects (AE) have been documented. Our goal was to provide a concise of their AE.

### Study Objective

To compare the safety of various treatment protocols for the treatment of COVID-19 patients. COVID-19 infected Mild patients, COVID-19 infected Moderate patients, COVID-19 infected Severe patients

## MATERIALS AND METHODS

**Study Design:** This was a retrospective, cross-sectional, observational and descriptive study.

**Study Setting:** The study was conducted at Dept. of Pharmacology, Heritage Institute of Medical Sciences, Varanasi, India.

**Ethical Aspects:** This study was approved by the Institutional Ethics committee, Heritage Institute of Medical Sciences, Varanasi.

**Study Population:** Data of COVID- 19 infected Patients who were admitted in Heritage Institute of Medical Sciences, Varanasi who fulfilled the inclusion criteria.

**Sample Size:** 524 patients (these numbers of patients fulfilled our study inclusion criteria)

**Data Collection:** The data of patients obtained from Indoor patients file of Heritage Institute of Medical Sciences, Varanasi.

The information recorded for this study was included adverse effect.

## RESULTS

In the mild group -1 [Table 1] patient's gastrointestinal adverse effect were most common. In this group loss of appetite and nausea was reported in

1.31 % patients is followed by vomiting and abdominal pain in 0.88 % patients each. Other adverse event reported in this group was headache in 0.43 patients.

In mild group 2 [Table 2] patient's also gastrointestinal adverse effect were most common. Diarrhea, abdominal pain and vomiting were reported in 0.98 % patients each. Headache was also reported in 0.98 % patient.

There was no adverse event reported in mild group 3 [Table 3] patients.

In moderate group-1 [Table 4] patient's gastrointestinal adverse effect were most common. Nausea, vomiting, Diarrhea, abdominal was reported in 1.49 % patients each. Dizziness, Delirium, changes in mood, Mania, depression was also reported in 1.49 % patients.

There was no adverse event reported in moderate group - 2 [Table 5] patients.

There was no adverse event reported in moderate group -3 [Table 6] patients.

There was no adverse event reported in severe group -1 [Table 7] patients.

In severe group -2 [Table 8] patient's diarrhea, nausea and vomiting was reported in 1.49 % patients each. Insomnia, irritability, psychosis, depression, anxiety, aggression and confusion were reported in 1.49 % patients.

**Table 1:**

<b>MILD (GROUP- 1) = 229</b>	
<b>Doxycycline + Ivermectin + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate</b>	
Loss of appetite	03 (1.31%)
Nausea	03 (1.31%)
vomiting	02 (0.88%)
Abdominal pain	02 (0.88%)
Diarrhea	00 (0.00%)
Headache	01 (0.43%)
Dizziness	00 (0.00%)
Rash	00 (0.00%)

**Table 2:**

<b>MILD (GROUP – 2) = 103</b>	
<b>Amoxicilin + Azithromycin + Ivermectin + Montelukast + Levocetirizine</b>	
Diarrhea	01 (0.98%)
Nausea	00 (0.00%)
Abdominal pain	01 (0.98%)
Vomiting	01 (0.98%)
Allergic reactions such as anaphylaxis	00 (0.00%)
QT prolongation	00 (0.00%)
Dizzines	00 (0.00%)
Headache	01 (0.98%)

**Table 3:**

<b>MILD (GROUP- 3) = 09</b>	
<b>Hydroxyclozoquine + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate</b>	
Abnormal electrical activity that affects the heart rhythm (QT-prolongation)	00 (0.00%)
Muscle weakness	00 (0.00%)
Insomnia, irritability, psychosis, depression, anxiety, aggression	00 (0.00%)

**Table 4:**

<b>MODERATE (GROUP – 1) = 67</b>	
<b>Doxycycline + Ivermectin + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate + Enoxaparin + Methylprednisolone + Formoterol + Budesonide</b>	
Loss of appetite	00 (0.00%)

Nausea	01 (1.49 %)
Vomiting	01 (1.49 %)
Diarrhea	01 (1.49 %)
Abdominal pain	01 (1.49 %)
Rash	00 (0.00 %)
Headache	00 (0.00 %)
Dizziness, Delirium, changes in mood, Mania, depression	01 (1.49 %)

**Table 5:**

<b>MODERATE (GROUP – 2 ) = 16</b>	
<b>Cefixime + Hydroxychloroquine + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate + Methylprednisolone + Formoterol + Budesonide</b>	
Abnormal electrical activity that affects the heart rhythm (QT-prolongation).	00 (0.00 %)
Muscle weakness	00 (0.00 %)
Insomnia, irritability, psychosis, depression, anxiety aggression and confusion	00 (0.00 %)

**Table 6:**

<b>MODERATE (GROUP – 3 ) = 12</b>	
<b>Amoxicillin + Hydroxychloroquine + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate + Enoxaparin + Methylprednisolone + Formoterol + Budesonide</b>	
Muscle weakness	00 (0.00 %)
Insomnia, irritability, psychosis, depression, anxiety, aggression and confusion	00 (0.00 %)
ringing in your ears	00 (0.00 %)

**Table 7:**

<b>SEVERE (GROUP -1) = 21</b>	
<b>Ceftriaxone + Favipiravir + Doxycycline + Ivermectin + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate + Methylprednisolone</b>	
Diarrhea	00 (0.00 %)
Nausea and vomiting	00 (0.00 %)
Loss of appetite	00 (0.00 %)
Rash	00 (0.00 %)
Headache	00 (0.00 %)
Dizziness, Delirium and changes in mood	00 (0.00 %)

**Table 8:**

<b>SEVERE (GROUP – 2) = 67</b>	
<b>Ceftriaxone + Remdesivir + Doxycycline + Ivermectin + Montelukast + Levocetirizine + Atorvastatin + Fenofibrate + Methylprednisolone</b>	
Diarrhea	01 (1.49 %)
Nausea and vomiting	01 (1.49 %)
Abdominal pain	00 (0.00 %)
Muscle weakness	00 (0.00 %)
Insomnia, irritability, psychosis, depression, anxiety, aggression and confusion	01 (1.49 %)
Allergic reactions such as anaphylaxis	00 (0.00 %)

## DISCUSSION

Total numbers of patents included were 524 based on the inclusion and exclusion criteria. Out of these, 383 were male and 141 were female.

This study analyzed the safety of various treatment protocol for mid, moderate and severe COVID 19 patients. In this study, assessment of various treatment protocols provided the data in support to find out the adverse events of COVID 19.

In this study, safety of various drug combinations in the treatment of COVID-19 was evaluated. Overall no major safety concerns were noted with various drug combinations. Most common adverse events were related to gastrointestinal system but there incidence was very minimal. Although, safety concerns are often not resolved in small scale clinical studies. Therefore, we recommend large scale clinical study to resolve the safety concerns, if any.

A study by Amir Sarayani et. al, 2021 reported, No significant safety signals were observed for HCQ/CQ when used alone using a disproportionality analysis approach with FAERS data. The finding of this study is similar to our findings.

A study by Nadia Mohammad Zadeh et. al, 2021 reported that most common side effects in Remdesivir studies for COVID-19 include respiratory failure and organ dysfunction, including low albumin, low potassium, low red blood cell count, low platelet count, which helps clots, and yellow skin discoloration. Reported side effects include gastrointestinal upset. The finding of this study is similar to our findings related to the gastrointestinal.

A study by Nadia Mohammad Zadeh et. al, 2021 reported that Azithromycin is an antibacterial drug and an acid-stable antibiotic that inhibits bacterial growth by interfering with their protein synthesis. Azithromycin is actively transported to the most

common side effects of azithromycin are diarrhea, nausea, abdominal pain, and vomiting. Allergic reactions such as anaphylaxis, QT prolongation, or Clostridium difficile infection have been reported with azithromycin. The finding of this study is similar to our findings related to the gastrointestinal.

## CONCLUSION

In this study, safety of various drug combinations in the treatment of COVID-19 was evaluated. Overall no major safety concerns were noted with various drug combinations. Most common adverse events were related to gastrointestinal system but there incidence was very minimal. Although, safety concerns are often not resolved in small scale clinical studies. Therefore, we recommend large scale clinical study to resolve the safety concerns, if any.

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