ORIGINAL ARTICLE

INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation Journal Home Page: www.ijrps.com

Partha's covid 19 protocol – A preliminary pilot study in Indian patients

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Article History:

Received on: 23 Jul 2020
Revised on: 20 Aug 2020
Accepted on: 09 Sep 2020

Keywords:

protocol,
contacts,
covid 19,
patients,
drugs

ABSTRACT

Covid 19 is a pandemic affecting many countries with countless deaths and morbidities. There are many drugs, and immune-boosting nutraceuticals developed to tackle the same. There are no strict guidelines still yet described. We propose a guideline or a protocol termed as Partha's protocol to counter every type of patient and contacts. In our early preliminary pilot study of 76 patients which included contacts, all were segregated into groups and received the drugs according to the protocol from Categories A to D. The basic strategies like social distancing and face masks continued. We had 19 positive cases and the rest as contacts. There was a need for minimal oxygen in two patients. Otherwise, there was no mortality. Among the contacts, there were only a few people (4 in number) who turned symptomatic, and none turned swab positive. This protocol seems to look like polypharmacy, but all these drugs were being used for different indications safely for many years. Hence it's unlikely to encounter any significant side effects. We also advise taking antibody titre of IgG in the post-exposure group. If it turns out to be positive, we suggest avoiding repeated quarantine on recurrent exposures. We did not measure viral load as we considered early symptoms with exhaustion as a marker. To wait for evidence and then to tackle contacts and less sick patients may be detrimental to countries like India because of its vast population.

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ISSN: 0975-7538

DOI: https://doi.org/10.26452/ijrps.v11iSPL1.3403

Production and Hosted by

IJRPS | www.ijrps.com

INTRODUCTION

Coronavirus infection in human started in December 2019 in the Wuhan state of China and has spread all over the world to infect millions of people and to kill lakhs of people. Even though there are many drugs and nutrition which are being investigated to counter the same, an ideal combination is yet to come (Suchitra and Parthasarathy, 2020a). Still, there are no proper guidelines to be followed for the different types of clinical presentation. The medical field is so far blind about the need for pharmacotherapy in contacts except for quarantine (Medhi *et al.*, 2020). In this setting, we prepared a protocol for each type of patients and followed up the patients to date.

Methods

This preliminary pilot study was done in STAMP covid care centre and ST hospital, Kumbakonam, India in June 2020- August 2020. A simple, convenient continuous sampling was done, and patients or contacts who were willing or consented to take the drugs according to the protocol after a proper

explanation was selected. These patients were subjected to RTPCR (Reverse transcriptase-polymerase chain reaction) in throat swabs. Then CT chest and necessary investigations, including acute phase reactants like C reactive protein assay, were done. A few patients arrived after testing positive for RTPCR. All patients and contacts were given according to the protocol described below (Partha's protocol). They were divided according to RTPCR results, chest CT findings and results of acute-phase reactants like CRP, D Dimer and Lymphopenia. The patients were treated as positive in CT chest when the CO-RADS score of 4 or more. (CO-RADS – COVID-19 Reporting and Data System) A score of three was not part of the drug protocol but watched for clinical deterioration. The patients who were very sick and needed hospitalisation were not considered. Any allergy to drugs described, including iodine, were excluded. The patients who reported with classical clinical features like fever, sore throat, myalgia, exhaustion, loss of smell and diarrhoea were subjected to investigations and started on category A. If a majority of these classical clinical features develop in secondary contacts, they were subjected to testing and watched after starting drugs as category A. By primary contact, we meant that such a person had a contact with a positive case notwithstanding the duration of association. By secondary contact, we meant; a consistent unprotected contact was present with a primary contact.

Partha's protocol

Category - A

Symptomatic covid RTPCR positive with negative CT chest and negative acute phase reactants – CT chest positive with waiting for RTPCR results

1. Favipiravir 1800 mg twice a day on day 1 followed 800 mg twice a day after food for seven days.
2. Hydroxychloroquine (HCQS) 200 mg twice a day - 7 days
3. Doxycycline 100 mg twice a day - 7 days
4. Ivermectin 12 mg once a day for three days
5. Methylprednisolone 8 mg twice a day for 7 – 10 days and decide later
6. Mandls paint in the throat and nose four times a day.
7. Rabeprazole 20 mg before food in the night Vitamin C, D and zinc tablets

Category – B

Patients with thrombo-inflammation in investigations

To admit in a non-hospital quarantine centre with basic medical facilities. To add Inj. Low molecular weight heparin 0.4 subcutaneous OD with Category A. A few cases where the acute phase reactants are borderline but positive CT chest. All patients with hypoxia or breathlessness or any other need of hospitalisation/Intensive care units are made as inpatients, and the drugs will be changed according to symptomatology parenterally.

Category -C

Primary contacts – having contact with RTPCR patients without adequate protection.

1. Primary contact with symptoms before test results are treated as A
2. Primary contact without symptoms come under C
3. oseltamivir 75 mg bd for seven days
4. Mandls paint in the throat and nose four times a day
5. Ivermectin 12 mg once a day for three days
6. Hydroxychloroquine 200 mg twice a day - 7 days
7. Methylprednisolone 4 mg bd
8. vitamins C, D and zinc

Category - D

Secondary contacts: These patients or individuals who were included those who had contacted asymptomatic primary contacts.

1. Mandls paint in the throat and nose four times a day.

2.Hydroxychloroquine 400 mg once a week for three weeks.

3. vitamins C, d and zinc

All patients are followed up for symptoms and looked for any deterioration and referred to admission and further treatment.

Results

Out of the 76 patients, forty-three were males. Nineteen were considered as corona out of which 11 were RTPCR positive while eight were only positive in CT chest, which means the CO-RADS score of 4 or more. (CO-RADS – COVID-19 Reporting and

Data System) A score of three was not part of the drug protocol but watched for clinical deterioration. Out of these 19, four were both swab test and CT chest positive. All these patients received Category A followed by three of them had a mild increase in D Dimer values, and hence heparinisation was started. These special parenteral treatments were followed in a quarantine centre with repeated measurements of acute-phase reactants. Among the primary contacts, 37 were asymptomatic but started on category C. Four contacts were symptomatic to institute category A. Sixteen grouped themselves into secondary contacts. Any transient contact of a positive case by a health worker with full protective equipment was not considered for the drugs. This is already described in ICMR (Indian Council of Medical Research) guidelines to start HCQS 400 mg weekly for nine weeks. In category D, we have added Mandls paint in the throat along with described guidelines. Out of the nineteen patients, two patients needed oxygen for a few days and then discharged. None of our contacts needed admission. Only four out the contacts turned symptomatic but with negative swab results. We advised ten days quarantine for positive cases, followed by seven and five days respectively for primary and secondary contacts. This quarantine period is invalid if the person develops symptoms, and the duration may extend to 10 days.

Drugs and Discussion

There are a lot of pros and cons of starting drugs for positive corona case. There are questions raised by a few to give symptomatic treatment for such cases instead of starting anti-viral drugs. We did resort to employing all drugs to get the best possible result from each one of them. (Jomah *et al.*, 2020) have described the usefulness of all antiviral, including Favipiravir, which is an RNA-dependent RNA polymerase inhibitor with antiviral activity against wide varieties of RNA viruses including SARS CoV 19. The dose described was exactly given by us in all the cases. As mentioned by the same Author (Jomah *et al.*, 2020), the side effect profile was many minimal. (Malek *et al.*, 2020) have described both the anti-inflammatory and antiviral properties of doxycycline. These two properties, even weak, may be useful for countering such a killer disease. Even though clinical evidence is lacking for in vivo studies, there are positive remarks even from ICMR about these two drugs – Ivermectin and doxycycline. This drug, ivermectin, has no major side effects in such short-term use. As such, there is a clear understanding of the pathophysiology of Covid 19 illness with a viral load in the early stages and an inflammatory response in the late stages.

As our patients are mostly in Day 3 – 5 . we needed to start both steroids and anti-virals. (Berton *et al.*, 2020; Liu *et al.*, 2020) A few researchers , have in their study looks better have in their studies have demonstrated the usefulness of steroids preferably earlier. They have further stated that there is no need to worry about the endocrine axis in this regimen. A few studies (Naveed *et al.*, 2020) have reported the usefulness of using oseltamivir in prophylaxis and treatment of covid 19 illness. (Suchitra and Parthasarathy, 2020b) A few authors have described the usefulness have described the usefulness of Mandls paint which is an old drug with new users because of its better taste and pharyngeal retention rather than iodine gargles. In yet another study, the addition of hydroxychloroquine sulfate (HCQS)is found to be useful in combating the virulence and the after-effects of a cytokine storm. (Gautret *et al.*, 2020). We accept that our protocols may be over drugged. We did not encounter major side effects with repeat liver and renal function tests. There was a feeling of fullness in the stomach for around 70 % of patients. There were no major side effects. All the 76 patients well tolerated all tablets. There is a general question against such type of poly-pharma protocols is "why?".

We answer that when we are not aware of the treatment guidelines in precision and prophylaxis is not established yet then "why not?' we can supply all patients with such protocols because all these drugs have been established drugs with no significant side effect issues and being used for decades except the anti-viral which is only in the clinical arena for a few years. We had a big advantage in following up the cases for effects and side effects. We had no admission rates with contacts. Our major hiccough was the non-repetition of nasal swabs as this is found not to be useful in terms of quantification and a repeat CT scan of the chest for want of mobilising manpower and financial constraints. (Calder, 2020) in his article has mentioned the role of immunity in tackling covid 19 with the help of supplements with Vitamin C, D and zinc. We planned to take antibody titre in contacts, and three of the contacts have already developed IgG antibodies out of the four tested. This positive antibody response throws light on the quarantine regimens of people with repeated exposure. A contact who has already developed an antibody response need not quarantine himself during further exposure. This is our preliminary suggestion. This may take a big shape if health personnel are advised to take routine monthly antibody titres and avoid repeated quarantine if positive. This may be a big boost to decrease the health workforce shortage. Hence, we have advised the con-

tacts to review for antibody titres. In a country like India with a vast population, waiting for evidence and restricted drug use may lead to avoidable morbidities.

CONCLUSION

In a small preliminary observational prospective pilot study of covid 19 cases and contacts, following a strict protocol may be useful to decrease the incidence of severe clinical illness. This excludes well-described methods like quarantine, distancing and face masks which were continued. This protocol needs further evaluation with randomised trials.

ACKNOWLEDGEMENT

Dr S. Thyagarajan and the staff of the COVID care centre for continued data collection and telephonic follow-ups.

Conflict of Interest

The authors declare that they have no conflict of interest for this study.

Funding Support

The authors declare that they have no funding support for this study.

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