

Potential therapeutic role of Coroprotect kit[®] in the management of Covid 19 patients: A case report

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ABSTRACT

Aim: There is no proven therapy against COVID-19 due to the unavailability of sufficient evidence. There is a common household practice in India to use medicinal plants against diseases. Ministry of AYUSH, Govt. of India had approved 20 medicinal plants which can be useful for COVID-19 care. We have developed an ayurvedic GP/AYU/2021/001 Kit containing COROPROTECT Tablet 1000 mg and COROPROTECT Dry Syrup 25 g for the treatment of patients with mild to moderate SARS-CoV-2 Infection. In this study, we evaluated with the COROPROTECT kit could be useful to COVID-19 management. **Patients and Methods:** This study included 200 COVID-19 RT-PCR positive patients with mild to moderate symptoms. Dosage of COROPROTECT Tablet included two tablets twice a day (12 h apart) for 10 days and COROPROTECT Dry Syrup included 10 ml syrup thrice a day (8 h apart) for 10 days. Recovery was defined as a negative report of COVID-19 based on RT-PCR. **Results:** Mean age of the patients was 41.05 ± 13.49 years ranging from 8 years to 70 years. Eighty percent of the patients were males. Twenty-seven patients were hospitalized. The most common symptom was fever ($n = 195$). Meantime to recovery (normalization of COVID report) was 5.24 ± 1.28 days ranging from 3 days to 9 days. We found a significant decrease in body temperature from baseline to day-3 after treatment with a Coroprotective kit ($P < 0.05$). **Conclusion:** Although earlier to say, COROPROTECT kit[®] could be effectively use against mild to moderate COVID-19 infection.

Keywords: COROPROTECT kit[®], COVID-19, herbal plants

Introduction

The outbreak of Coronavirus SARS-Cov-2 disease (COVID-19) in Wuhan (China) in late 2019 and its worldwide spread has caused hundreds of thousands of deaths so far. As of July 2020, the disease seems to be mostly affecting Europe and the Americas. Most people infected with the COVID-19 virus will experience mild-to-moderate respiratory illness and recover without requiring special treatment. Older people and those with underlying medical problems such as cardiovascular disease, diabetes, chronic respiratory disease, and cancer are more likely to develop serious illness.^[1] Teens and adults without underlying medical conditions are asked to self-manage their symptoms in isolation with a minimum of drugs (paracetamol, if

fever is high) and lifestyle adjustments (increased rest and hydration). However, most of the current guidelines do not specifically advise on how to treat cough, one of the main symptoms, which, apart from being very debilitating, contributes to the spread of the virus.

There is not yet any evidence-based specific therapy for COVID-19, and the real efficacy and safety of current therapeutic approaches will need further scrutiny when enough multi-site clinical data become available. Predictably, patients will largely try to increase their well-being at least by self-administering cough suppressing medication (natural or not) plus natural medication or supplements to combat cold/flu symptoms. These are readily accessible both in retail commerce and community pharmacies.

We agree in that COVID-19 is not the common flu, but the WHO definition is clear in that it is a mild, self-limiting condition and, therefore, fitting the boundaries of self-prescription, moreover if the patients have not been tested for the virus.^[1] In that sense, there is a need to clarify the real potential and safety profile of herbal medicines

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to scientifically substantiate future recommendations on their benefits and risks of use them.

Patients and Methods

Two hundred patients with COVID-19 RT-PCR positive were included in this study at January 2021 over a period of September 2021.

The sponsor of the proposed study has developed an ayurvedic GP/AYU/2021/001 Kit containing COROPROTECT Tablet 1000 mg and COROPROTECT Dry Syrup 25 g for the treatment of patients with mild to moderate SARS-CoV-2 Infection. Dosage of COROPROTECT Tablet: included two tablets twice a day (12 h apart) for 10 days and COROPROTECT Dry Syrup included 10 ml syrup thrice a day (8 h apart) for 10 days.

The patients were excluded if they had a history of hypersensitivity to any ingredient of the drug, requiring intensive care unit admission at screening, women known or suspected to be pregnant, lactating women, patients with severe renal impairment, and patients with severe hepatic impairment, history of myocardial infarction or epileptic episodes.

The study was approved by the Institutional Ethics committee. All the study participants were included if they agreed to provide their consent in the study.

Data were recorded into Microsoft® excel workbook 2019 and exported into SPSS v21.0 (IBM, USA) for statistical analysis. Categorical variables were presented as frequency, percentage. Quantitative variables were presented as mean or standard deviation. Time to recovery at different duration was compared using paired *t*-test. $P < 0.05$ was considered statistically significant.

Results

The results of the present report include baseline characteristics, effect of body temperature, time to recovery, which represents the complete understanding about the aim of the study and achieve the objectives.

Baseline characteristics

Mean age of the patients was 41.05 ± 13.49 years ranging from 8 years to 70 years. Eighty percent of the patients were males. Twenty-seven patients were hospitalized. The most common symptom was fever ($n = 195$), the data represented in Table 1.

Effect of body temperature

We found a significant decrease in body temperature from baseline to day-3 after treatment with coroprotective kit ($P < 0.05$) [Figure 1].

Time to recovery

In this study, mean time to recovery (normalization of COVID report) was 5.24 ± 1.28 days ranging from 3 days to 9 days.

Table 1: Baseline characteristics

Characteristics	Frequency	Percentage
Sex		
Male	162	81
Female	38	19
Symptoms		
Fever	195	97.5
Cough	177	83.5
Body ache/Headache	181	90.5
Fatigue	90	45
Shortness of breath	28	14
Hospitalization		
Yes	27	13.5
No	173	86.5

Data expressed as frequency and percentage

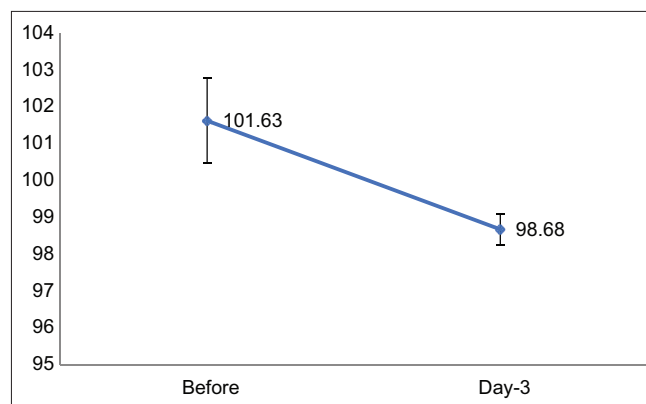


Figure 1: Trend in change of temperature after treatment with COROPROTECT kit. X-axis shows time while Y-axis shows temperature in Fahrenheit

Discussion

The current pandemic generates fear in the population who seek solutions to prevent or alleviate the symptoms of the disease since they feel the only resource available to them is self-help, self-care, and self-medicate.^[1] Therefore, it has been reported that some people resource to self-medication^[3] and others to the use of medicinal plants^[4] as potential but unproven methods to ameliorate and/or prevent symptoms related to COVID-19. The Ministry of AYUSH, Government of India has recommended 20 medicinal plants for COVID-19 care.^[5]

COROPROTECTIVE kit contains the compounds which have been recommended for COVID-19 care. In our study, the COVID-19 patients were recovered in a mean duration of 5.24 days. The time to recovery was defined as the normalization of RT-PCR investigation. COROPROTECTIVE kit contains *Withania somnifera* as a major ingredient. Its selective-Th-1 upregulating activity of WS has been demonstrated in mouse models,^[6] which also seems relevant in the management of COVID-19. Available data indicate that WS may be a good candidate for clinical repurposing in COVID-19 management.^[7] In an interim analysis, *W. somnifera* has been found to be equally effective as hydroxychloroquine after 8 weeks of therapy with mild adverse events.^[8]

Another predominating compound Shudh Shilagit is found to be effective against a number of diseases. Although several clinical trials evaluating the efficacy of Shilagit are undergoing, the use of Shilagit is found to be based on people's choice. A newspaper reported that a number of residents of capital Kabul and Facebook users believed that shilajit cures COVID-19 infection, but health professionals rejected the belief as unproven.^[9,10]

Another predominating constituent, *Tinospora cordifolia* in COROPROTECT kit is found to show high binding efficacy against SARS-CoV-2 targets involved in attachment and replication of the virus. Hence validating the merit of using *T. cordifolia* in the clinical management of infection caused by SARS-CoV-2.

Conclusion

The present study provides fruitful outcomes in earlier recovery with COVID-19 irrespective of hospitalization with the use of COROPROTECT kit. However, further randomized controlled trial comparing its efficacy and safety with other drugs will be required to generalize the findings.

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