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# Retrospective evaluation of the efficacy, safety and satisfaction of AyurCoro3 : A patient-reported outcomes study

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## ABSTRACT

**Background:** At the backdrop of absence of any approved treatment for COVID-19 infections, Ayurvedic treatment can be explored for its potential. AyurCoro-3 is a combination of *Gomutra* (bos indicus urine), hot water, turmeric, *Turati churna* (potassium Alum), candy sugar (*khadisakhar*), *Bos indicus* milk with two teaspoons of *Go Ghrut* (Ghee) with antimicrobial and immunomodulatory properties. The present study evaluated the responses from individuals who consumed Ayurcoro-3. **Methods:** A retrospective observational study was carried out based on the participants who consumed Ayurcoro-3. Participants were asked about their reasons for taking the drug, whether as prophylaxis/treatment, duration of symptoms following the drug intake compared to baseline, their satisfaction with Ayurcoro-3, and adverse events. **Results:** Two thousand participants were recruited, and majority consumed Ayurcoro-3 as a prophylactic drug (1285, 64.25 %). Amongst those who were symptomatic, 317 had cough and 328 had fever, and 299 had positive RT-PCR test. The mean (SD) duration of symptoms were significantly shorter following the intake of Aurcoro-3 as follows: cough [before: 4.64 (3.26), after: 2.26 (1.34) days;  $p < 0.05$ ], fever [before: 4.16(2.40), after: 2.15(1.34) days;  $p < 0.05$ ], breathlessness [before: 5.56 (2.66), after: 2.30 (1.19) days;  $p < 0.05$ ], and weakness [before: 5.69 (3.08), after: 2.36 (1.13) days;  $p < 0.05$ ]. Majority of the participants stated that they were very satisfied with Ayurcoro-3. None of the participants reported any serious adverse reaction and only few adverse events were reported. **Conclusion:** We found that Ayurcoro-3 to be highly effective and safe in preventing/treating COVID-19 related symptoms and the patients are highly satisfied with the response.

**Key words:** Coronavirus infections, COVID-19, Ayurveda, Complementary and Alternative Medicine, prophylaxis.

## INTRODUCTION

Coronavirus disease (COVID-19) has shaken the entire world from November 2019 affecting over 184 million patients infected and 3.96 million deaths worldwide as of 2<sup>nd</sup> July, 2021. No proven therapy exists except

for remdesivir that is approved only for patients requiring hospitalization.<sup>[1]</sup> Use of complementary and alternative medicine (CAM) in the form of Chinese medicine, Ayurveda, Yoga, Unani, Siddha, and Homeopathy (AYUSH) have been explored for their usefulness in managing COVID-19 patients.<sup>[2]</sup> Close to two-thirds of Indian patients were observed to use one of the CAM for treating their disease mainly due to the fear of adverse drug reactions due to allopathic drugs.<sup>[3]</sup> This fraction is significantly more with cancer patients where the treatment is often sub-optimum and cure is uncertain.<sup>[4]</sup> A study from 495 COVID-19 patients from an isolation center in India revealed that 128 (25.8%) patients used 161 CAM products and home remedies where more than half of them used Ayurvedic medicine during the treatment and following discharge from the hospital.<sup>[5]</sup> Given the

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intensity and the risk of infections with mutant viruses, and the shortage of allopathic medicines in catering to the needs of millions of patients, a cheap and easily prepared alternative (a CAM product) is preferred. We prepared an Ayurvedic combination medicine 'Ayurcoro-3' that consisted of *Bos Indicus* distilled urine (BIDU), potassium alum (PA), rock candy (RC), *Bos Indicus* ghee (BIG) and *Bos Indicus* Milk (BIM). The ingredients in this combination have been proven to possess anti-microbial, antipyretic, and immune boosting properties.<sup>[6-8]</sup> Ayurcoro-3 is dispensed through pharmacy stores as well as patients can order it in the product website.<sup>[9]</sup> We carried out the present study to evaluate the efficacy and safety of Ayurcoro-3 in preventing COVID-19 infections amongst the consumers.

## METHODS

### Study ethics and study design

The study was initiated after obtaining approval from the Institutional Ethics committee for biomedical research (EC/NEW/INST/2019/245) between January and May 2021. The present study was carried out in the Bhakti Vedanta Hospital and Research Institute, Mumbai, India. Verbal consent was obtained from each study participant. We complied with the latest Declaration of Helsinki guidelines.

### Study participants

Ayurcoro-3 is sold from our product website and the details of the patients who have ordered the medicinal product is retained by the Ayurveda Department in the Institute. We retrieved this data and contacted the patients who have consumed Ayurcoro-3 either for the purpose of prevention or treatment of COVID-19 infections.

### Intervention

The Food and Drug Administration has licensed the ingredients of Ayurcoro-3 as drug with immunomodulatory properties. AyurCoro-3 medicine consists of the following with the instructions provided to the consumers:

- *Bos indicus* urine/hot water/turmeric to be gargled twice a day. First gargle one hour prior to

lunch around 12 noon and second gargle around 9 PM.

- *Turati Churna* (potassium Alum) with candy sugar (*Khadisakhar*) in half a glass of warm water mixed with *bos indicus* urine 10 ml, orally. The first dose of this intervention should be initiated one hour post lunch, the second dose after two hours post first dose, and the third dose after two hours following the second dose.
- One glass (200 ml) of pure *Bos indicus* milk with two teaspoons of *Go Ghrut* (Ghee) to be administered after one hour of the third dose.

### Study procedure

We contacted the individuals who have ordered Ayurcoro-3 from the product website. The following details were obtained from each study participant: reason for purchasing Ayurcoro-3 (for the purpose of preventing COVID-19 infection with/without exposure to COVID-19 positive patients/ or for treatment purpose as the individual experienced flu-like symptoms such as cough, fever, running nose, and myalgia); duration of exposure/symptomatic period and dates of consumption of Ayurcoro-3.; date and result of investigations pertaining to COVID-19 infections such as real time-polymerase chain reaction (RT-PCR) test, computed tomography test; and presence of any co-morbid diseases such as diabetes, systemic hypertension, chronic kidney disease, bronchial asthma/chronic obstructive pulmonary airway disorder; and any side effects following the consumption of Ayurcoro-3 medicine.

A pre-validated six-item scale was used for evaluating the satisfaction of the Ayurcoro-3 consumers. The face validity of the questionnaire was confirmed by the expert panel that constituted experts from the Ayurvedic medicine and statistician. The internal validity of the scale was confirmed in 30 participants and the reliability was evaluated by re-administering the same scale in this subset of the study population after 7 days. The responses from this subset of patients were excluded from the main analysis.

### Statistical analysis

Descriptive statistics was used for representing the demographic variables. Kappa statistics was used for evaluating the reliability of the questionnaire and a high degree of agreement was observed with the score of 0.87. As this study was primarily intended to evaluate the feedback from the consumers, we did not estimate the sample size. Numerical variables were tested for their distribution using Kolmogorov-Smirnov test and accordingly Student's T test was used for evaluation of the significance between the groups. A p-value of  $< 0.05$  was considered significant.

## RESULTS

### Demographics

Two-thousand and two-hundred and thirty participants were contacted of which 2000 were finally recruited. Table 1 summarizes the demographic characteristics of the study participants. Majority of the study participants were in the middle-aged category between 41 and 60 years.

### Response from the study participants

Majority consumed Ayurcoro-3 as a prophylactic drug (1285, 64.25 %). Amongst those who were symptomatic, 317 had cough and 328 had fever, and 299 had positive RT-PCR test. The mean (SD) duration of symptoms was significantly shorter following the intake of Aurcoro-3 as follows: cough [before: 4.64 (3.26), after: 2.26 (1.34) days;  $p < 0.05$ ], fever [before: 4.16(2.40), after: 2.15(1.34) days;  $p < 0.05$ ], breathlessness [before: 5.56 (2.66), after: 2.30 (1.19) days;  $p < 0.05$ ], and weakness [before: 5.69 (3.08), after: 2.36 (1.13) days;  $p < 0.05$ ].

Majority of the participants stated that they were very satisfied with Ayurcoro-3 (Figure 1).

### Adverse events

None of the participants reported any serious adverse reaction and only few adverse events were reported (Table 2).

## DISCUSSION

We carried out the present study in 2000 patients who took Ayurcoro-3 mainly as a part of preventive

measure with few with symptoms, and positive for COVID-19 infection. Following the intake of Ayurcoro-3, all the symptoms subsided immediately and almost all of them were highly satisfied with the Ayurvedic medicine. Only mild adverse events were reported.

Several Ayurvedic medicines have been shown to be useful in ameliorating the signs and symptoms of COVID-19 and been debated to be used as vaccines [10]. *Tulsi*/Holy Basil/ *Ocimum sanctum*, *Dalchini* / Cinnamon / *Cinnamomum zeylanicum*, *Sunthi* / Ginger / *Zingiber officinale* and *Marich* / Black Pepper / *Piper nigrum*, and Ashwagandha are some other herbal medicines that have been explored for their potential in curing Covid-19 infections.<sup>[11]</sup> The modern allopathic medicines that have either been proven or are under exploration for their therapeutic benefit for Covid-19 are expensive, and unavailable due to tremendous demand. Considering the fact that more than two-thirds of the population in the low- to middle-income countries use one of the CAM products and that many of such nations have a national policy on CAM use, it is imperative that CAM products with potential for preventing (by immune enhancement) or treating Covid-19 infections have more acceptance than the allopathic medicines amongst the general population. This is also supported by the data on the number of clinical trials registered and conducted in India where 61% were related to AYUSH interventions.<sup>[12]</sup> The ingredients used in Ayurcoro-3 are easily available and affordable and so the chances of demand supply imbalance is minimal. Although we did not elicit, we anticipate that this could be the most important reason for the high satisfaction amongst most of our study participants.

The strength of this study is that we have elicited the response from the end-users of the CAM product. Patient-reported outcomes are the crucial and most important objective measures that should drive the use of new medicinal product rather than based on just the clinical/laboratory parameters. However, the present study is also limited in not having a control group other than baseline duration of symptoms amongst those with suspected/confirmed Covid-19 infections.

## CONCLUSION

We observed that our Ayurvedic medicine 'AyurCoro-3' was observed with better satisfaction amongst the consumers and was also effective and safe in preventing/treating COVID-19 infections.

## FUNDING

The funder of the study had no role in the study design, data collection, data analysis, data interpretation or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

**Table 1. Demographic characteristics of the study participants (N=2000).**

Parameters	Values
Age (years) <sup>α</sup>	42.2 (15.1)
Male <sup>β</sup>	1256 (62.8)
<b>Co-existing diseases</b>	
Hypertension <sup>β</sup>	95 (4.8)
Ischemic heart disease <sup>β</sup>	3 (0.2)
Diabetes <sup>β</sup>	100 (5)
Diabetes and systemic hypertension	46 (2.3)
<b>Presenting symptoms</b>	
Cough <sup>β</sup>	317
Breathlessness <sup>β</sup>	41
Tastelessness <sup>β</sup>	13
Fever <sup>β</sup>	328
Weakness	110
<b>Reason for consuming Ayurcoro-3</b>	
Prophylactic	1285 (64.25)
Symptomatic	259 (12.95)

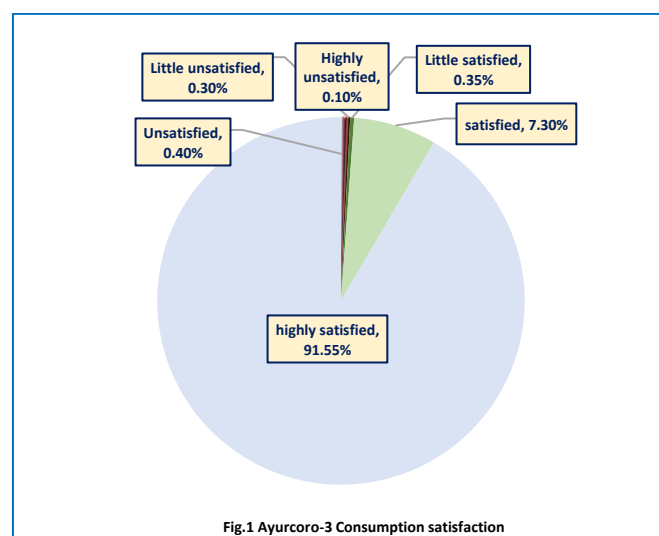
Admitted Patients	291 (14.55)
Exposed to symptomatic Patients	165 (8.25)
<b>Patients positivity rate</b>	
RT-PCR	299 (14.95)
Rapid antigen test	24 (1.2)
High resolution computed tomography	6 (0.3)

$\alpha$  – represented in mean (SD);  $\beta$  – represented in n (%).

**Table 2. Adverse events reported amongst the study participants.**

Event	Number of participants reporting
Nausea	6
Loss of appetite	5
Headache	4
Flatulence	5
Epigastric pain	1
Disturbed sleep	3

**Figure 1. Responses to the satisfactory scale.**



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