ORIGINAL RESEARCH

Homoeopathic Medicine *Arsenicum album* 30 C for Covid-19 in 2020: A Retrospective Analysis from Mass-level Data

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ABSTRACT

Background and Objective • Homoeopathy has played a notable role in managing epidemics in the past. The Ministry of Ayush, Government of India, declared *Arsenicum album* 30 C as a prophylactic for Covid-19, which was followed by the distribution of the medicine across India. The Central Council for Research in Homoeopathy (CCRH) collected post-prophylactic consumption data of individuals from various colleges over months, which created a data pool. Considering the importance of these mass-level data and their possible impact on public healthcare decisions, the information gathered from this heterogeneous population cohort was subjected to a retrospective data analysis to observe the incidence of Covid-19 in the community.

Methods • Data from 50 colleges from February–August 2020 showed that 10.6 million people in 13 states of India received prophylactic medicine during the study period. The data was collected from individuals three weeks following prophylactic consumption for a retrospective analysis. The incidence of Covid-19 was assessed.

Results • The data of 584 980 individuals who met the study criteria were included in the analysis. The incidence of Covid-19 in the population cohort was 13.58 per 10 000-person weeks (95% CI, 13.04 to 14.14), which remained near-constant over time despite the increasing disease burden in the country (12.87 to 14.52 per 10 000-person weeks). Consumption of the prophylactic significantly reduced the risk of contracting Covid-19 in high-risk groups as compared to their counterparts.

Conclusion • The study concludes that *Arsenicum album* 30 C has a potential prophylactic effect against Covid-19. Further controlled studies are recommended to establish a causal relation. (*Altern Ther Health Med.* [E-pub ahead of print.])

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INTRODUCTION

The World Health Organization (WHO) declared Covid-19 a 'pandemic' after 114 countries reported more than 118 000 cases, and the unfamiliar virus had claimed 4291 lives by March 11, 2020.[1] Despite rigorous containment measures at the global level, the pandemic caused more than 515.2 million confirmed cases and over 15 million deaths worldwide as of May 6, 2022.[2,3] Although the mass vaccination drive provided some respite, the rise in the number of global breakthrough infections posed another challenge.[4-6]

Like other countries, India was also adversely affected by Covid-19. Beginning with a slow pace in the initial phase, the number of cases in India grew steadily, spiraling to 800 000 by mid-July 2020.[7,8] Like many nations worldwide that made their best efforts to tackle the virus, India faced the pandemic with resilience and fortitude despite its healthcare challenges, as the government employed a myriad of strategies for the prevention and containment of the disease.[9,10]

AYUSH systems of medicine are an integral part of the healthcare delivery system of the country. The success of homoeopathic medicines in managing past epidemics[11,12] testify

to their 'genus epidemicus' approach, wherein a suitable prophylactic medicine, which is identified to match the characteristic totality, is built after observing several cases of the epidemic.[13] In the absence of any known conventional treatment or vaccine for Covid-19, the Ministry of Ayush (MoA) issued a public health advisory suggesting a homoeopathic prophylactic in January 2020.[14] *Arsenicum album* 30 C was recommended by experts as the 'genus epidemicus' after assessing the clinical presentation of the disease,[15] its affinity for the respiratory system, and its usefulness in previous studies on Influenza-like illnesses (ILI).[16,17]

Many provincial governments soon adopted the central advisory, which was followed by door-to-door endeavors for mass distribution of *Arsenicum album* 30 C by various government, private, and voluntary organizations, and, especially, homoeopathic medical colleges. As these efforts snowballed, millions of people in multiple states, heterogenous in various aspects, and residing in urban, semi-urban, and rural areas, received the medicine.[18-21] Subsequently, along with a series of regulatory provisions by the government, many research studies (prophylactic and treatment) were initiated to validate the usefulness of *Arsenicum album* and other homeopathic medicines for Covid-19.[22]

Early in the pandemic, the Central Council for Research in Homoeopathy (CCRH) developed a structured format to capture information about the distribution and response of people who consumed *Arsenicum album* 30 C as a prophylactic for Covid-19, which was made available to colleges, private organizations, state government institutes, etc.

The homoeopathic colleges across India that were recording this information shared their data with CCRH, which generated a sizable data pool over months. These mass-level data may reflect the real-time effect of the consumption of the prophylactic and have a possible impact on the healthcare decisions of the public. Thus, the information gathered from this heterogeneous population was subjected to a retrospective data analysis to assess the incidence of Covid-19 in the community.

MATERIAL AND METHODS

Design and Data Source

A retrospective data analysis was carried out based on the data received by CCRH from 50 homoeopathic medical colleges, collected between February and August 2020. These data reflected that a total of 10.6 million people residing in 49 localities across 34 districts in 13 states of India received the homoeopathic prophylactic medicine *Arsenicum album* 30 C through 50 colleges after the release of the central advisory by the MoA. At various points during this period, these 34 districts were labeled 'red zones' or hotspots showing high community transmission of Covid-19.[10]

Study Population

Data from individuals of all ages, male/female genders, who consumed one dose (adult: four pills comprise one dose; children: two pills comprise one dose) of *Arsenicum album* 30 C, once daily, for three days, as per the advisory, and could be followed up by the teams at the colleges telephonically/in-person upon the completion of three weeks after the prophylactic consumption, during February–August 2020, were considered as the study population. Individuals with missing data on age and co-morbidities were removed from the study population before the analysis. The state-wise distribution of the study population is reflected in Figure 1. The flow diagram of the study participants is given in Figure 2.

Figure 1. State-wise Distribution of the Study Population

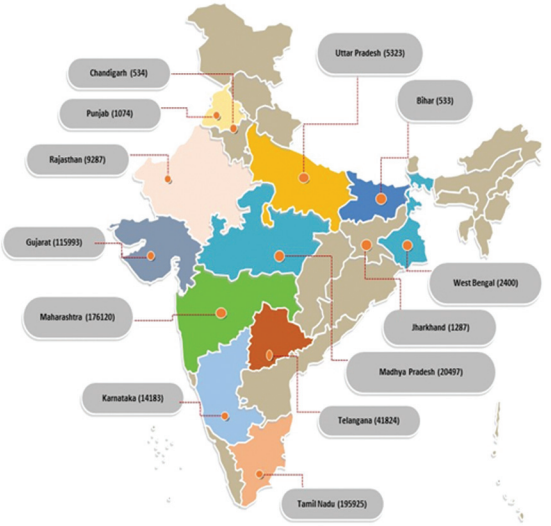
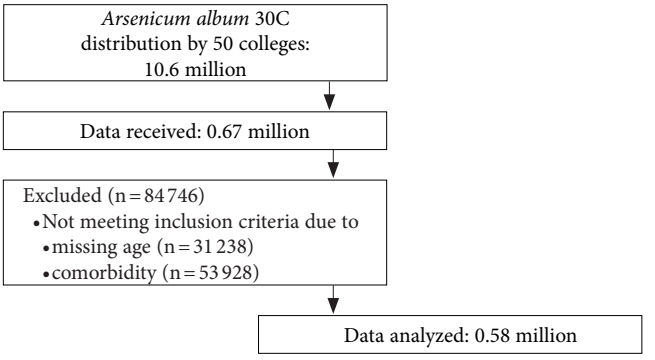


Figure 2: Flow Chart of Study Participants



Data Collection

The teams collecting the data comprised homoeopathic doctors. The teams confirmed the intake of three doses of *Arsenicum album* 30 C three weeks before the in-person/telephonic interview. The information was recorded from each individual or an adult member (head of the family) after seeking verbal consent.[23] Besides basic demographic information, the data included information about the development of any symptoms related to Covid-19 in the three weeks following prophylactic consumption. If any person reported symptoms related to Covid-19, detailed information about their health status, duration of symptoms, and laboratory testing results for Covid-19 were collected. Data regarding hospitalization were recorded as well.

Outcome Measures

The outcome was the incidence of Covid-19 as per the case definition notified by the National Centre for Disease Control (NCDC), Directorate of Health Services, Ministry of Health & Family Welfare, Government of India.[24] The effect of risk factors on the incidence of disease and the clinical presentation of the Covid-19 population along with the duration of suffering were also assessed.

Suspected Case. Acute onset of two or more of the following symptoms: fever with or without chills, myalgia/general weakness/fatigue, cough, headache, sore throat, loss of taste, loss of smell, runny nose, difficulty in breathing, loss of appetite in adults/poor feeding in children, nausea/vomiting, diarrhea, and altered mental status.

Probable Case.

A. A suspected case who is in contact with a confirmed case or epidemiologically linked to a cluster of confirmed cases.
B. An asymptomatic person who is a high-risk contact of a confirmed case or epidemiologically linked to a cluster of confirmed cases.
C. If clinically suspected by a physician.
D. Death, not explained otherwise, in an individual with respiratory distress preceding death and who was in contact with a probable or confirmed case or epidemiologically linked to a cluster of confirmed cases.

Laboratory-confirmed Case. A person with laboratory confirmation of Covid-19 infection, irrespective of clinical signs and symptoms.

Other Definitions

High-risk groups. Those individuals who were of above 60 years of age or male or presenting with any co-morbidity.

Ethics

Ethical approval for anonymous data analysis and publication was accorded by the Institutional Ethics Committee of CCRH in the 24th meeting of the Ethical Committee held on August 25, 2020, vide 1-3/2019-20/CCRH/Tech/24th EC.

Statistical Methods

Data gathered from the individuals were entered in predesigned spreadsheets and entries were double-checked at the level of the college teams before being shared with CCRH. Incidence rates (IRs) were calculated as person-weeks considering that the numerator was the number of events and the denominator was the sum of the person-time contributed by each study participant during the study period. The incidence of Covid-19 was also assessed in stratified sub-groups based on age, gender, comorbidity, and the periods of lockdown and unlock. A crude incidence rate ratio was calculated for sub-groups based on age, gender, and comorbidity. Continuous data were expressed as mean ± SD. Categorical data were expressed in numbers or percentages. A Chi-square test was done to assess the association between categorical data. All the results were expressed with 95% confidence intervals (CIs). Statistical significance was set at $P < .05$ (two-tailed). The analyses were performed using IBM SPSS Statistics for Windows, version 20 (IBM Corp, Armonk, NY, US).

RESULTS

Demography

The analysis included the data of 584,980 people collected over 7 months (February–August 2020) and meeting the defined criteria (Figure 2).

The mean age of the population cohort was 36.88 ± 18.29 years, the lowest being 1 month and the highest being 96 years. The study population comprised 59.07% (n = 345 571) males and 40.92% (n = 239 383) females, of which 7.83% (n = 45 833) reported suffering from single or multiple co-morbidities. Commonly reported co-morbidities included hypertension and diabetes. While 0.59% (n = 3479) of participants reported having chronic lung disease, an even more meager percentage reported having diseases like chronic heart disease, chronic kidney disease, etc. Almost half of the population was employed: around 0.17% (n = 981) were healthcare/hospital workers while 0.23% (n = 1370) were police personnel. The demographic characteristics of the study population are given in Table 1.

Outcomes

Incidence of Covid-19. The study population was observed for 1 754 940 person-weeks. During the study period, 0.41% (n = 2384) of the study population had Covid-19. These were composed of 5.24% (n = 125) laboratory-confirmed cases and 94.76% (n = 2259) suspected/probable cases. The overall IR of Covid-19 in the study population was 13.58 per 10 000-person-weeks (95% CI, 13.04 to 14.14). The incidence of Covid-19 remained near-constant over the study period (12.87 to 14.52 per 10 000-person-weeks) despite community outbreaks all over India, as seen in Figure 3 ($\chi^2 = 1.26$; $P = .974$). Comparable IRs were observed in the study population during the periods of lockdown (April–May 2020; IR = 13.41 per 10 000-person-weeks; 95% CI, 12.73 to 14.1) and unlock (June–August 2020; IR = 13.84 per 10 000-person-weeks; 95% CI, 12.9 to 14.84). Around 1.43% (n = 14) of healthcare workers and 0.73% (n = 10) of police personnel who were continually exposed to the risk reported Covid-19.

Covid-19 Incidence in High-risk Groups. Sub-group analysis was done by stratifying the study population based on risk factors such as age, gender, and co-morbidities.

Males who consumed *Arsenicum album* 30 C were at a reduced risk of contracting Covid-19 than females (RR = 0.90; $P = .015$). A reduced risk was also observed in the co-morbid population (RR = 0.65; $P = .0001$) and in persons above 60 years of age, who remained protected as compared to their counterparts despite their added risk (RR = 0.79; $P = .001$).

Table 1. Demographic and Epidemiological Characteristics of the Study Population

Variable(s)	Summary Value (n = 584 980)
Month-wise data distribution n (%)	
February	518 (0.09)
March	21 856 (3.74)
April	61 541 (10.52)
May	308 692 (52.77)
June	162 468 (27.77)
July	9645(1.65)
August	20 260 (3.46)
Age n (%)	
Overall age (mean ± SD), in years	36.88 ± 18.29
0–10 years	43 546 (7.44)
11–20 years	77 532 (13.25)
21–30 years	114 294 (19.54)
31–40 years	114 087(19.50)
41–50 years	96 166 (16.44)
51–60 years	79 374(13.57)
Above 60 years	59 981 (10.25)
Gender n (%)	
Male	345 571 (59.07)
Female	239 383 (40.92)
Others	26 (0.00)
Occupation n (%)	
Employed/self-employed[a]	285 696 (48.84)
Student	108 917 (18.62)
Household worker/homemaker	43 503 (7.44)
Child	14 082 (2.41)
Retired	10 720 (1.83)
Unemployed	5692 (0.97)
Police personnel	1370 (0.23)
Healthcare workers/hospital staff	981 (0.17)
Media/sSocial activists	170 (0.03)
Not reported	113 849 (19.46)
Co-morbidities n (%)	
Hypertension	27 237 (4.66)
Diabetes mellitus	20 294 (3.47)
Chronic lung disease	3479 (0.59)
Others	3960 (0.68)

[a]Includes professions like shopkeepers/chemists/laborer's/IT professionals/teachers/farmers/artists/security personnel/trainers/hospitality services/skilled workers or tradesmen (blue collar job)/engineers etc.

Figure 3. Incidence Rate of Covid-19 per 10 000 Person Weeks Over Time (February to August 2020)

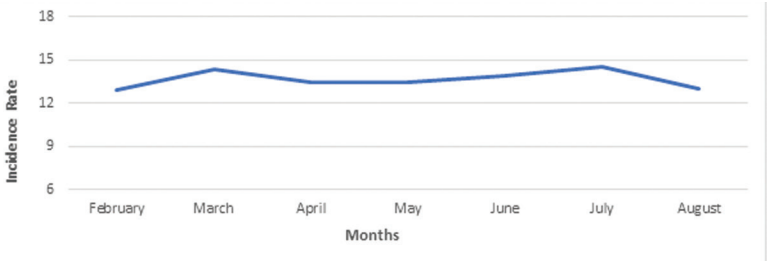
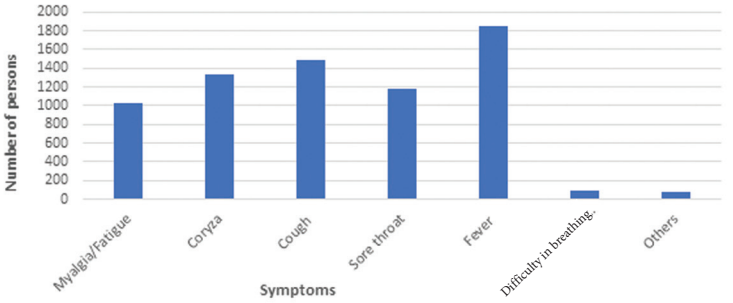


Figure 4. Symptoms Reported in the Covid-19 Population



Note: Others include loss of smell, loss of taste, headache, diarrhea, loss of appetite, and nausea/vomiting.

Table 2. Incidence of COVID-19 in Study Population and Risk Groups

Variables	Events n (%)	Incidence (95% CI)/ 10 000 person weeks	Rate ratio (95% CI)	
			Univariate	*P* value
Covid-19 population	2384 (0.41)	13.58 (13.04 to 14.14)	–	–
Age				
Below 60 years	2185 (0.42)	13.30 (13.38 to 14.47)	1	Baseline
Above 60 years	199 (0.33)	11.06 (09.58 to 12.71)	0.79 (0.68 to 0.92)	.0016
Gender				
Female	1034 (0.39)	14.40 (13.54 to 15.31)	1	Baseline
Male	1350 (0.43)	13.02 (12.34 to 13.74)	0.90 (0.84 to 0.99)	.015
Co-morbidities				
Non-Co-morbid	2260(0.42)	13.97 (13.40 to 14.56)	1	Baseline
Co-morbid	124 (0.27)	9.02 (07.50 to 10.75)	0.65 (0.53 to 0.76)	<.0001

Abbreviation: CI-confidence interval.

The Chi-square test of association indicated that a significant proportion of persons in the three risk groups, namely those above 60 years of age ($\chi^2 = 9.45$; $P = .002$), males ($\chi^2 = 5.93$; $P = .014$), and those with a co-morbidity ($\chi^2 = 22.99$; $P = .0001$), remained protected against Covid-19. No significant difference in the proportion of persons affected with Covid-19 was seen during the phases of lockdown and unlock ($\chi^2 = 0.54$; $P = .461$). The stratified IR and risk ratio (RR) for Covid-19 are summarized in Table 2.

Clinical Presentation of the Covid-19 Population

Fever was the most frequently reported symptom observed in 77.77% (n = 1854) of the Covid-19 population, followed by cough in 62.37% (n = 1487), coryza in 56.08% (n = 1337), sore throat in 49.37% (n = 1,177), myalgia/fatigue in 43.20% (n = 1 030), difficulty in breathing in 4.03% (n = 96) while only 3.19% (n = 76) population reported other symptoms like loss of smell, loss of taste, headache, diarrhea, nausea/vomiting, and loss of appetite (Figure 4). Fever with

cough was the most reported symptom combination in the Covid-19 population.

Around 35.36% (n = 843) individuals reported the presence of two symptoms and 34.14% (n = 814) reported the presence of three symptoms. Only 0.42% (n = 10) individuals confirmed the presence of six symptoms in combination.

Time Taken for the Resolution of Symptoms

On average, symptom resolution in the Covid-19 population occurred in 3.47 ± 1.07 days: 4.00 ± 2.64 days in confirmed cases and 3.44 ± 0.89 days in suspected/probable cases.

Hospitalization

Around 99.16% (n = 2364) of individuals in the Covid-19 population recovered with self-medication/medical advice and treatment from a doctor under home isolation. Only 0.84% (n = 20) went to a hospital/Covid care center.

Other Cases

There were 0.19% (n = 1085) symptomatic individuals who presented with a single symptom and were not considered as suspected/probable cases of Covid-19 as per the NCDC definition. Myalgia was the most prominent symptom reported by 59.54% (n = 646), followed by coryza in 14.01% (n = 152), and cough in 10.97% (n = 119).

DISCUSSION

This study found that the overall incidence of Covid-19 in the study population was 13.58 per 10 000-person-weeks, which was comparable with the results of a controlled cohort study undertaken by Nayak et al in the containment zones of Delhi.[25] The incidence of Covid-19 remained near-constant over the study period, ranging between 12.87 to 14.52 per 10 000-person-weeks despite increased rates of infection/community outbreaks of Covid-19 in the country as the pandemic progressed from February 2020 to August 2020. Although the numbers cannot be compared due to the unavailability of data on suspected/probable cases of Covid-19 in India in the public domain, it can be seen that in contrast to the study population, the country witnessed a steady upward trend in cases during this period, with projections still being under-reported.[26-28]

The study results from this pragmatic setting reflect the potential prophylactic effect of *Arsenicum album* 30 C in a heterogeneous community differing in terms of epidemiological characteristics such as geographical location, climate, culture, socioeconomic status, ethnicity, etc.

Being the second-highest populous country in the world[10,29] with a huge burden of co-morbidities,[10,30,31] reported poor health behaviors,[32] and around 65%–68% of the rural population with the highest overall burden of disease globally,[33] the burden of the pandemic was complicated further for India. Despite these factors, India has managed the pandemic relatively better than its counterparts, especially in terms of incidence and fatality rates.[34-37] Though it is difficult to predict the factors responsible for this, the advisory by the government was followed by the mass-scale distribution of Ayush medicines, especially *Arsenicum album* 30 C. It is noteworthy that in the state of Gujarat alone, 50% of the population consumed *Arsenicum album* 30 C during the first wave.[21]

The intake of *Arsenicum album* 30 C demonstrated a reduced risk of Covid-19 infection in all the risk groups,[38,39] namely persons above 60 years of age, males, and persons with co-morbidities. Further, a significant association between the decreased incidence of Covid-19 and consumption of *Arsenicum album* 30 C was observed, suggesting the potential of the medicine in reducing the added risk in these individuals.

Unlike the rising caseload seen in India during the unlock phase of the first wave, similar incidence rates of Covid-19 were observed in our study population during the lockdown and unlock phases. Covid-19 infection remained much lower—around 1% among frontline workers (healthcare workers and police personnel) in our study population–when compared with the available prevalence data from India, which ranges between 5%-11%.[40,41]

Our study reports fever as the most frequently reported symptom in the Covid-19 population and fever with cough as the most prevalent symptom combination. Around 0.19% of the symptomatic cases presenting with a single symptom and not abiding with the NCDC definition were not reported as having Covid-19 in the study. However, a recent review of the predictive value of symptoms of Covid-19 suggests the importance of symptoms such as myalgia, fatigue, and headache as "red flags" and fever and cough as having 50% sensitivity for a diagnosis of Covid-19.[42,43]

It was also observed that 99% of the Covid-19 population recovered with self-medication/medical advice from a doctor under home isolation while less than 1% went to a hospital/Covid care center. However, these numbers are inconclusive of the actual need for hospitalization due to variations in state policies and the availability of hospital beds as the pandemic progressed. While the clinical outcomes of the disease may be governed by other therapeutic and individual factors, a future study to observe if consumption of *Arsenicum album* 30 C played any possible role in modulating the clinical pathogenesis attributable to Covid-19 can be an interesting incursion.

Being a retrospective data analysis of a population cohort, this study has some limitations. Recall bias[44] in study participants during telephonic/personal follow-ups may be a limitation; however, such data collection leads to under-reporting rather than over-reporting of events, and, hence, does not overestimate the results of the study. A causal relation between the consumption of medicine and protection against Covid-19 cannot be drawn in the absence of a control group;[45] however, observational studies are recommended to estimate the protective effect of an intervention.[46] However, the results of this study are found to be comparable with the findings of a controlled cohort study undertaken in the containment zones of Delhi by Nayak et al[25] and a retrospective cohort study undertaken by Daruiche et al in Brazil.[47]

Syndromic surveillance is an accepted method of disease surveillance by central and provincial governments in cases of health emergencies, in a resource-scarce setting, or the emergence of a new disease, like an epidemic.[48] Due to the dearth of available testing facilities during the early phase of the pandemic in India, symptomatic prevalence of the disease was recorded as per the government-notified definition in the study. It is noteworthy that the increased reporting of symptomatic cases/Covid-like illnesses/influenza-like illnesses is associated with increased reporting of laboratory-confirmed cases of Covid-19.[49] Moreover, in India, 90 cases were not recorded for each diagnosed Covid-19 case.[26] However, the study falls short in estimating the infection rate and asymptomatic burden of the disease.

The study could not conclude anything about the effect of other Ayush prophylactic medicines that may have been consumed by the population due to the absence of such data. However, a study by Nayak et al[25] concludes that other Ayush medicines did not have an interaction or modifying effect on the incidence of Covid-19 in the population which consumed *Arsenicum album* 30 C.

Like many known successes with homoeopathic medicines in past epidemics such as the Spanish Flu, cholera, and dengue,[11,12,50,51] the findings of this study are evocative of the potential of a carefully-selected homoeopathic 'genus epidemicus' in new or lesser-known diseases.

This study provides potential positive evidence of the prophylactic potential of *Arsenicum album* 30 C, based on the findings of a controlled prophylactic field study[25] and, thus, suggests that it can be explored as a viable alternative or a concomitant measure in case of difficulties in developing and disseminating vaccines, pathogenic mutations, or even the rising incidence of breakthrough infections.

CONCLUSION

The study concludes that *Arsenicum album* 30C has a potential prophylactic effect against Covid-19. Further controlled studies are recommended to establish a causal relation.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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AUTHOR CONTRIBUTIONS

AC: Conception of the work and writing of the manuscript, data curation & analysis, and contribution to all facets of the work. DN: Conceptualization and guidance for revision of the manuscript, data analysis, and interpretation. SP: Data curation and analysis, review of the literature. RR: Data analysis and interpretation. AK: Guidance for the conduction and conception of the retrospective data analysis and interpretation and revisions in the manuscript. Covid 19 study group: Distribution of medicines and data acquisition. All authors approved the final manuscript.

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Table S1. Covid-19 Study group (Names of Homoeopathic medical colleges and contributors given in alphabetical order)

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Ahmedabad Homoeopathic Medical College, Gujarat Gaurav Bhatt, Heena Rawal, Nidhi Dave, Vani Nanavati, Vinod Patel
Bakson Homoeopathic Medical College, Uttar Pradesh Ajay Kumar Bhati, Alok Kumar, Amit Kumar, Sunil Chand, Vishal Singh Chauhan
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Dhondumama Sathe Homoeopathic Medical College, Maharashtra Devyani D Deshmukh, Maneesha Solanki, Sayli Kelkar
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Shree Mahalaxmiji Mahila Homoeopathic Medical College & Hospital, Gujarat Anshika Ajit Patil, Himanshu Praful Chandra Thakkar, Hujefa Ibrahim Kosiya, Kajal Gaurang Kumar Patel, Keval Rajeshbhai Soni, Krusha Rahul Panjwani, Pallavi Jayesh Jadav, Shloka Sanket Bhatt
Shree Shamalaji Homoeopathic Medical College, Gujarat Anwar Husein I Kachba, Keyoor V Soni
Shri B. G. Garaiya Homoeopathic Medical College and Hospital, Gujarat Ashish Narsana, Ishita Siddhpura, Komal Chhag
Smt. A. J. Savla Homoeopathic Medical College, Gujarat Pinakin N Trivedi, Rajesh R Patel, Yashavant P Patel
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