

Management of Covid-19 patients with indigenous formulations in home settings- Case reports of two patients

Neeta Kumar,¹Nalini Tripathi,² Mukesh Nandave³

¹ Scientist-E, Indian Council of Medical research (ICMR) Head Quarters, New Delhi

² Scientist-C, Department of Community Medicine, Vardhman Mahavir Medical College & Safdarjung Hospital, New Delhi,

³ Professor, Pharmacology, Delhi Pharmaceutical Sciences and Research University (DPSRU), New Delhi, India

Abstract:

This is to report 2 cases experiencing action of indigenous medicine in controlling Covid-19 symptoms in the home setting, without any requirement of hospitalization. Covid-19 (SARS-CoV-2), a viral disease by novel coronavirus, impacted 220 countries. Although, numerous attempts have been made for the management and treatment of Covid-19 with various drugs, traditional Ayurveda and Siddha has been widely reported to be effective in treating viral diseases through altering innate adaptive immune response and inhibition of virus attachment to body cells. It is found to inhibit attachment of virus to human cell, hence reducing viral load induced cytokine storm, inflammatory over reactions in the body of patients and inhibition of community spread. The experience of 2 cases reported here showed how senior citizens with various co-morbidities recovered from covid 19 and remained healthy without sequelae or side effects even after 6 months of follow-up. These observations are vital clues for a large population-based study and ongoing clinical trials. Mechanism of action of Sidha and Ayurvedic medicines like *Kabasura Kudineer*, *Sitopladi*, *Triphala* are well published and highly recommended for affecting viral entry and immune regulatory pathways. With no side effects, secondary infections and action, these regimens pave the ways for safe and effective cure for Covid-19.

Keywords: Antiviral, Ayurveda, Covid-19, inflammatory response, medicinal herbs, Siddha medicine.

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*CORRESPONDING AUTHOR:

Dr Neeta Kumar,

Scientist E, ICMR Hqrs, Room no 214, First floor
Indian Council of Medical Research, Ansari Nagar,
New Delhi-110029.

Email neetakumar50@gmail.com

Introduction:

With second wave March 2021 onwards, globally 17.9crores persons suffered and 38.8 lakhs deaths with India reporting 3.91 lakhs deaths ranking 2nd in prevalence, 3rd in Deaths. [1] Appropriate and timely action of prevention and management by Government of India helped during first wave of Covid-19 pandemic. However People living with pre-existing health conditions such as heart disease, diabetes, and respiratory conditions were considered at higher risk of complications, sequelae, and death due to Covid-19. Hence reporting is highly needed about the response observed in such high risk cases with use of Indian Sidhha, Ayurvedic traditional formulations to manage fever, cough, body-ache of Covid-19.[2]

Case 1: Patient description

This is about a case of senior citizens, female aged 64 years having co-morbidities of heart disease (coronary artery diseases-CAD), and arthritis and were found having high grade fever, headache, body ache, difficulty in breathing. Diagnosis of Covid-19(SARS-CoV-2) infection was confirmed by real-time Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) nasopharyngeal swabs on 20 September 2020. She had no history of contact however visited a public gathering of 40-50 persons in an open park, 3 days ago.

Case history of case 1:

The patient living in South Delhi, belonging to an upper-middle socio-economic group, having arthritis for 24 years, coronary artery disease 14 years, had sudden onset of high fever (102°F to 104°F) with severe body ache, fatigue, breathlessness, sore throat since 17 September 2020. She underwent tests at the Government health facility after 2 days of uncontrolled symptoms where she was diagnosed positive for Covid-19. Results of pathological tests showed raised CRP at 184 mg/L and ferritin 116000ng/ml. D dimer level

was 1200ng/ml indicative of severe inflammation. Pulse oxymeter showed 78% oxugen, pulse rate 120/minute. An absolute lymphocyte count was lower than normal range -950cells/ μ l.

Treatment prescribed:

The patient consumed tablet Paracetamol (500 mg three times a day) for high fever, along with steam inhalation from day one of the symptoms. After the diagnosis of Covid-19, on third day of fever, she was advised for home quarantine with the added treatment of Doxycycline, Vitamin C, Azithromycin, ZnSo₄, fluids, and juices, which she complied without any relief in symptoms. On 5th day of continued high-grade fever, she consumed two tablets of *Kabasura Kudineer*, *Sitopladi*, *Triphala*, *Amruta* (Giloy) (500 mg tablets of each twice a day) with warm water on 22 September. After consuming she started feeling relief of symptoms instantly and became completely symptom free by the next day. She continued treatment for 7 days. No further complication or residual symptoms remain till date, post 6 months of her Covid-19.

Case 2: Patient description:

A male aged 68 years living in East Delhi, is a known hypertensive, diabetic and suffering from coronary artery disease and on regular medications- Atenolol 25 mg, Glyciphage 500 mg, Disprin 325 mg, and simvastatin 10 mg twice a day for his illnesses.

Case history of case 2:

He had a history of attending a public gathering of a relative's cremation 3 days ago. His symptoms started with high-grade fever, headache, and weakness on 17th September 2020. On examination: The temperature was 102°F to 104°F with transient dips after taking paracetamol, but no regular relief from symptoms for 3 days. On day 3 i.e. 20th

September 2020, results of pathological tests came as positive for COVID-19. Serum SARS-CoV-2IgG was -17.00. He was tested for complete blood count, liver, kidney function tests, thyroid profile, urine routine microscopic, lipid profile, blood sugar as prescribed by a local physician. All reports were within normal range except mild rise of lymphocytes as 46% against reference range of 20-40% of DLC.

Treatment Prescribed:

Oral Paracetamol 500 mg 4 hourly for 3 days then Azythromycine 500mg two times a day (BD) after food Hydroxychloroquine 500 mg (BD) and Tab Vitamin C 500 mg (BD) from 3rd day after getting Covid 19 test report. After no relief from fever, headache and body ache on 5th day, he was advised *Kabasura Kudineer* (500 mg, 1 tab BD), *Sitopaladi* (500 mg, 1 tab BD) and *Triphala* tablets (500 mg, 1 tab BD) for 7 days. Immediately after consuming the regimens, symptoms of Covid-19 started reducing in severity. His fever reduced on 24th September 2020, and symptoms completely dissolved on 2nd day of consumption of Siddha-Ayurvedic medicines. No further complications and residual illness were observed till 6th month post-Covid-19.

Discussion:

Age more than 60 yr with presence of diabetes and hypertension were significantly associated with severe COVID-19 disease and 3 patients died (2.6% mortality) when clinical characteristics and outcomes compared for adult Covid-19 positive patients admitted to tertiary care hospital at Chandigarh, India, from April 1 to May 25, 2020. Patients with co morbidities were found more vulnerable to complications also.^[3] The cases reported here are important in view of the advanced age and comorbid conditions, severity of symptoms and their ongoing treatments considered as

high-risk conditions at the time of Covid-19 infection.^[3]

In India recovery from Covid-19 remains high as on 23rd June 2021 2.91 crore of Covid 19 recovered out of infected 3 crores.^[4-5] Italy with 9.26% death tops the cross country fatality rates (CFR). CFR of China was 3.9% and 2.8% in India. Apart from timely preventive measures undertaken by The Government of India the sharp difference of mortality across country data warrants evaluation of treatment strategies.^[4] Review of pathological changes in autopsy findings of patients with COVID-19 show endothelial damage and formation of microthrombi with multi-organ involvement and, ultimately, multi-organ failure; However trials did not prove that, Covid-19 patients had increased thrombotic risk, despite being treated with heparin despite its anti-coagulant effect. Hence cytokine storm and inflammations generated by Covid-19 virus need different approach of treatment.^[6]

Review of the existing literature for pathology mechanism, shows that Covid-19 strain was causing a sharp rise in inflammatory reactions in the form of cytokine storm resulting in disseminated intravascular coagulation in the brain (stroke) or heart (infarct), lung (reduced oxygen –hypoxia, presenting as atypical pneumonia) and related complications.^[6] Existing reports and research findings show that age old Indian/indigenous regimens effectively curtail inflammatory over-reactions, multisystem inflammatory syndrome, thrombi formation happening due to allergens and viral infections.^[7-8] Ingredients of regimen (*Kabasura Kudineer*, *Triphala*, *Sitopaladi*) used by two cases reported here were reviewed from published literature and mentioned in Table 1, 2 and 3.

Table-1: Ingredients of *Kabasura Kudineer* and their actions: ^[9-11]

Sanskrit name/	Common name/	Botanical name/	Active ingredient
Chukku/	Ginger/	<i>Zingiberofficinale/</i>	Zingiberene
Thippali/	Pippali /	<i>Piper longum/</i>	piperine
Lavangam/	Clove /	<i>Syzygiumaromaticum/</i>	eugenol
Cirukanchoriver/	Dusparsha /	<i>Tragiainvolucrata/</i>	Costunolide
Akkirakaramver/	Akarakerebha /	<i>Anacycluspyrethrum/</i>	Pyrethrin
Muliver/	Kokilaksha /	<i>Hygrophilauriculata/</i>	Apigenin
Kadukkaithol/	Haritaki/	<i>Terminaliachebula/</i>	Chebulic acid
Adathodeielai/	Mdabarnut/	<i>Adhatodavasica/</i>	Vasicine
Karpooravalli/	Ajwain/	<i>Coleus amboinicus/</i>	Myrtenol
Kostam/	Kusta/	<i>Saussurealappa/</i>	Costunolide
SeenthilThandu/	Guduchi /	<i>Tinosporacordifolia/</i>	CordifolisideB
Siruthekku/	Bharangi	<i>Clerodendrum serratum/</i>	Cavacol
Nilavembu/	Kalmegha	<i>Andrographispaniculata/</i>	Andrographaide
Vattathiruppiver/	Rajapata/	<i>Sida acuta/</i>	Carvacol
Koraikizhangu/	Musta /	<i>Cyperus rotundus/</i>	Amentoflavone

Table-2: *Triphala* Ingredients: ^[12]

Sanskrit name	Common name	Botanical name	Active ingredient
Amalaki	<i>Amla</i>	<i>Phyllanthus emblica</i>	Ascorbic acid, Gallic acid, Nicotinic acid, Ellagic acid, Linoleic acid, Linolenic acid
Bibhitaki	<i>Baheda</i>	<i>Terminalia bellirica</i>	Gallic acid, Tannic acid, Ascorbic acid, β -sitosterol, Ellagic acid, Chebulic acid, Mannitol, Oxalic acid, Galloyl, Galactose, Fructose
Haritaki	Harad	<i>Terminalia achembula</i>	Gallic acid, Tannic acid, Syringic acid, Epicatechin, Ascorbic acid, Chebulinic acid, Anthraquinone, Phosphoric acid

Table-3: *Sitopaladi* Ingredients: ^[13]

Sanskrit name	Common name	Botanical name	Active ingredient
Twak bark	<i>Tejpatta</i>	<i>Cinnamomum zeylanicum</i>	Cinnamaldehyde
Ela seed	Elayachi	<i>Elettaria cardamomum</i>	Cardamom
Pippali fruit	Pippali	<i>Piper longum</i>	Piperine
Vamsalochan		Siliceous Concretion	
Sharkara	Cane sugar	<i>Saccharum officinarum</i>	Carbohydrate

Ingredients combined in equal proportions of 6.66% of each compound. Ingredients are tested for actions like Antibacterial Anti-viral Anti-inflammatory Antioxidant Hepatoprotective Anti-cancer Neuroprotective Antimicrobial Anti-parasitic Anti-asthmatic Anti-malarial Antihelminthic Antidiabetic

Antifungal Antispasmodic Antipyretic Analgesic Cytoprotective Immunomodulatory Anticonvulsant Antihyperglycemic Abortifacient Wound healing Hypoglycaemic Cytotoxic Antiseptic Antimelanogenic and show different level of part or some of the actions of these ingredients^[14,-16]

Ministry of AYUSH guidelines mention about *Kabasura Kudineer* as effective Siddha medicine consisting of 15 herbal ingredients, each of them having unique characteristic features of its own.^[8] This composition is extensively aimed for boosting the lungs, improving respiratory mechanism and treating infectious conditions like cough, cold, fever and other respiratory infections.^[2] This composition became quite well-known during the times of flu in past, owing to its therapeutic and curative qualities.

Many studies have documented anti-inflammatory, antipyretic and antibacterial properties of *Kabasura Kudineer* Chooranam.^[14-16] Effect of aqueous extract of *Kabasura kudineer choornam* (AEKKC) have shown significant anti-inflammatory, antipyretic and antibacterial activity evaluated in Coimbatore. AEKKC showed significant in vitro anti-oxidant activity by terminating the actions of free radicals. The AEKKC (200 mg/kg and 400 mg/kg) studied for its anti-inflammatory activity using carrageenan and histamine-induced inflammation as compared to paracetamol (150 mg/kg), Diclofenac (20 mg/kg) as the standard for the antipyretic activity in Brewer's yeast-induced pyrexia model proved AEKKC possesses significant ($P < 0.05$) anti-inflammatory activity which was evident with a reduction in mean paw edema volume in both carrageenan and histamine-induced inflammatory models. The potential activity of extract considered due to the presence of phenols, flavonoids, and other phytochemical constituents present in it.^[14]

Screening of *Kabasura Kudineer* against COVID-19 through targeting of main protease and RNA-dependent RNA polymerase of SARS-CoV-2 by Molecular Docking Studies provided the evidence for the action of 74 different constituents of this formulation acting on two critical targets.^[16] That is the main protease and SARS-Cov-2 RNA-dependent RNA polymerase target through molecular docking experiments. The

molecular docking was done by using AutoDock Tools 1.5.6. Of the 74 compounds 50 compounds yielded docking results against COVID-19 main protease while 42 compounds yielded against SARS-cov2 RNA-dependent RNA polymerase. This research has concluded that AEKKC has the lead molecules that inhibit COVID-19's target of the main protease and SARSCov-2 RNA-dependent RNA polymerase.^[16]

Triphala (tri = three and phala = fruits) (Chinese term San-Teng), is composed of three equal proportions of fruits of all 3 ingredients.^[17] *Triphala* a polyherbal formulation shows inhibitory activity on microbial growth caused by *Streptococcus mutans* and *Lactobacillus*. Ayurvedic formulations like *triphalamashi* exhibit antimicrobial activity attributed to phenolic compounds and tannins in triphala^[1]. The oral administration of *triphala* found reducing the blood sugar, various applications in medical field like laxative, eye rejuvenator, anti-inflammatory, antiviral, found effective in headache, dyspepsia, ascites, leucorrhea, also used as a blood purifier analgesic, antiarthritic, and anti -aging properties. It is also prescribed for fatigue, to reduces oxidative stress and infectious diseases such as tuberculosis, pneumonia, AIDS, periodontal diseases. due to oxidative stress.^[18]

Sitopaladi claimed to have an antihistaminic effect, Immunomodulatory, Anti-inflammatory, Antibacterial, Adaptogenic, fights against allergies by inhibiting the release of histamines, inflammatory mediators from mast cells in our body and stabilizes them, Digestive And Appetizer by carminative action. Anti-tussive activity of this medication is assign to its ability to affect the central nervous system and suppress a cough, reduces Inflammation and Free Radicals- damaging effects of free radicals, improve anemia due to sub-chronic inflammation, has strong α -amylase inhibition activity to prevent the body from absorbing

starches, thus prevent the spike in blood sugar after meals and controlling postprandial hypoglycaemia.^[19]

Apart from above formulations, there are many other such anti-inflammatory, anti-microbial formulations described in Ayurveda considering age gender, prakriti, comorbidity and ongoing treatments, stage of disease.^[20] There was state policy of Tamilnadu Government for distribution of *KabasuraKudineer*.^[21] Guidelines of Ministry of AYUSH, Government of India also issued guidelines to promote use of the indigenous herbs for Covid-19 prevention/ management however its implementation scale and community use data should be collected at large scale.

There are studies reporting faster recovery using indigenous methods.^[19] Randomised Controlled Trials (RCTs) registered on clinical trial registry (i.e. CTRI registration number: CTRI/2020/06/025800) have evaluated the efficacy of Ayurveda in the management of 120 mildly affected Covid-19 cases using Vyaghryadi, Pippali, Shunthi (*Zingiber officinale* Rosc.) and Guduchi (*Tinospora cordifolia*).

Jaipur study (CTRI/2020/05/025273) Traial with 1 g of Giloy Ghanvati (*Tinospora cordifolia*) and 2 g of Swasari Ras (traditional herbo-mineral formulation) and 0.5 g each of *Ashwagandha* (*Withania somnifera*) and *Tulsi Ghanvati* (*Ocimum sanctum*) *Anutaila* (nasal drops) quantified serum levels of interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF- α), and high sensitivity C-reactive protein (hs-CRP)-to predict severity and survival on day 1 and day 7 and found 20 times lesser than those in the placebo group.^[22] Community spread possibility was lower with Ayurvedic indigenous medicine group as they become negative at faster pace^[22]

Ayurvedic and Siddha preparations when compared with Remdesivir, 100 % recovery within 7 days with Ayurvedic/ siddha

treatment as compared to 15 days with Ramdesivir.^[22-24] One RCT comparing done with combination of Siddha drugs Vasantha kusuma

karammathirai, Thippilirasayanam, Adathodai manapagu and Kabasurakudineerat Omandurar Government Medical College Hospital Tamilnadu showed accelerated recovery with Kabasurakudineer for Covid - 19 patients as compared to standard treatment Group. The Siddha

medicines like Kabasurakudineer and Adathodaimanapagu quoted in classical Siddha texts are approved by Drug and Cosmetic Act. The Siddha Formulary of India, Part I is published by Department of Health and Family Welfare, Government of India. Higher recovery percentage was recorded in In another recent study group on Siddha add-on showed better recovery (66.67 %) when compared with standard treatment alone (22.67%)^[24-25].

Where, Hydroxychloroquine (HCQ), Remdesivir, plasma therapies found ineffective and moved out of guidelines, the indigenous herbs showing promising outcomes with survival and reduced community spread are considered now.^[24,26] Due to outcome of such studies, many more are now ongoing/ exploring and documenting effect of Siddha ayurvedic preparations like *Kabasura*, *tripphala*. At CTRI, currently 67 trials are ongoing with traditional medicines. Three studies are exclusively for therapeutic efficiency of *Kabasura Kudineer*.^[27]

Most of the community data is missed due to absence of home based data collection system. Only one ICMR Task Force study of health account scheme collected community end data of fever, Flu like illnesses. Despite many high risk factors for India (i.e. dense population, social distancing difficulties due to close and highly knitted social structure, younger age nation, genetic predisposing factor in terms of low D allele frequencies in Asian, mutation in terms of high virulent virus type, 'B', prevalent in patients across East Asia, low

inherent immunity, climate of India not favouring Covid-19) lower mortality is observed (14.5 % in Italy versus 3.17% of India).^[27-28] The comparison of treatment strategies is not done sufficiently so credit of low mortality, difference of outcome due to various management system, indigenous regimens require large scale community and hospital based data comparing home (using traditional) versus standard managements and its outcome, hence studies with proper design are required.

Conclusion:

Considering observations from the cases, reported here and circumstances of Covid 19 pandemic the evidence-based use of indigenous medicines should be considered for management.

Limitation of study:

- In the cases reported here both the cases did not repeat Covid 19 test after becoming symptom free (facility of home test was not available that time) hence time taken in becoming Covid 19 negative is not recorded, however symptoms resolved in one day time in both the cases.
- There is mixing of other regimens like paracetamol etc in initial 3-4 days hence role of Siddha- Ayurvedic medicines as stand-alone regimens will be clearer if treated on these medicines from the very beginning of symptoms. More clinical and community data on this is required.
- Though no side effects reported in cases reported here upon taking indigenous composition however, it is always best to seek the advice of an Ayurvedic physician.
- In our cases this formulation was found safe while it was consumed with allopathic medicines and medicines for ongoing chronic co-morbidities however proper pharmacokinetic studies are required to verify it.

Consent of Patients:

Consent of Both cases has been taken to report their case without their identifier personal details disclosure.

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