

Global regulatory scenario of indigenous medicines with respect to Covid-19

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Abstract

As coronavirus disease-19 (COVID-19) instances still exist in an alarming manner, there are no efficient and effective remedies or treatment to fight against the deadly coronavirus infection. The morbidity rate concerned with COVID-19 also shoots up in the case of individuals with a weak immune system such as children, older patients, or sufferers with already have health-related problems. In the present, herbal medicinal products can serve as healing agents, to assist human beings in combating the COVID-19 infection through boosting their immune responses. Herbal remedies must fulfill the regulatory standards of quality, safety, and efficacy to get market approval. At present, the requirements and regulations of herbal remedies differ based on the regulatory requirement of country, which raises a dispute for the manufacturing of standardized herbal remedies in the global market. The main intention of this review article is to compile and discuss various traditional herbal medicine and their remedies to assist in strengthening the immune system and even plays the better role in fighting against coronavirus.

Key words: coronavirus disease-19, medicines, clinical trial, treatment, herbal remedies

INTRODUCTION

Coronavirus is a recently detected strain of coronavirus disease-19 (COVID-19) that induces illness similar to the common cold to fatal illnesses in individuals throughout the world.^[1] The common symptoms of COVID-19 include fever, cough, and shortness of breath. In severe cases, pneumonia may occur and ultimately lead to organ failure and even death. The disease originating from Wuhan, China, and subsequently been reported in virtually every nation of the world.^[2] Mainly there are four genera of COVID-19 existing includes alpha-, beta-, gamma-, and delta-coronavirus. Alpha and beta stem from mammals, especially bats, although gamma- and delta-coronaviruses are of avian origin.^[3] The World Health Organization (WHO) has consequently announced COVID-19 as a global pandemic. The WHO is continuously tracking it and frequently updates the information's concerning its mortality, spread, and morbidity.^[4] Around

80% of COVID-19 cases present with mild symptoms required only primary health care. Rest 15% of COVID-19 cases need urgent medical care at secondary health-care hospitals. The remaining 5% are critical cases requiring intensive care and subsequently require a tertiary medical care unit equipped with intensive care unit.^[5] In the wake of the coronavirus pandemic, there have been numerous interests in a manner to improve one's immune system.^[6] At present, there are no available vaccines or specific medicines for the treatment of COVID-19. Treatment modalities have been considered, including traditional medicine. Therefore, we aimed to systematically review traditional medicine and herbal compositions recommended for treating patients with

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COVID-19.^[7] Aromatic herbs, culinary spices, medicinal plants, and herbal teas have used to boost immunity.^[8]

For treating the COVID-19, two distinct phytotherapeutic compounds are used. The first option is the herbal remedies that have preventive effects specifically boosting the immune responses, such as *Astragalus membranaceus* and *Echinacea purpurea*. The next option is the herbal remedies with therapeutic outcomes that have a distinct antiviral mechanism of action such as *Sidoides* and *Sambucus nigra*.^[9]

In this review, we aim to report historical records on the antiviral activity of a particular diet and herbal medicine on influenza virus, severe acute respiratory syndrome coronavirus (SARS-CoV-1), and SARS-CoV-2. This will promote the use of dietary therapy and herbal medicine as complementary COVID-19 prevention therapies, given the current absence of an effective drug and vaccine against COVID-19/SARS-COV-2. Several doctors and researchers have already attempted to use herbal medicines on clinical trials against SARS-CoV-2.^[10]

CHINA

In China, the pandemic is under control due to the government strong measures, public surveillance, and utilization of both Conventional Western Medicine and Traditional Chinese Medicine (TCM).^[11]

Lung Cleansing Detoxifying Decoction (LCDD)

LCDD is a cocktail of formulation developed based on four formulas depicted in Treatise on cold pathogenic and miscellaneous disease. The chemical composition of LCDD is complex; control of the consistent quality of an herbal remedy is challenging, and its action mechanism in treating COVID-19 is unknown.

Composition

LCDD mainly consists of 21 ingredients – *Ephedra sinica*, *Atractylodes macrocephala*, *Cinnamomum cassia* (twig), *Alisma plantago* – Aquatica, *Bupleurum chinense*, *Scutellaria baicalensis*, *Pinellia ternate* (pretreated with ginger and potassium alum), *Aster tataricus*, *Asarum sieboldii*, *Tussilago farfara*, *Agastache rugosa*, *Iris domestica*, *Dioscorea polystachya*, *Prunus armeniaca*, *Citrus aurantium*, *Licorice* (roasted), ginger, orange peel, *Polyporus umbellatus*, *Wolfiporia extensa*, and *Gypsum* (CaSO₄ · 2H₂O).

Uses

The combination of these activities likely counters COVID-19 by simultaneously inhibiting viral propagation, easing the symptoms of pneumonia, and suppressing the viral infection-induced cytokine storm.^[12]

LianhuaQingwen (LH) Capsules

LH capsules increase the recovery rate in COVID-19 patients. However, it has not proved efficacious in preventing severe infection from currently infected individuals or reducing median viral assay conversion time.

Composition

LQC mainly consists of 11 herbal ingredients including *Fructus forsythiae* (Lianqiao), *Herba ephedrae*, *Flos lonicerae japonicae* (Jinyinhua), *Rhizoma dryopteridis*, *Semen armeniacae amarum* (Kuxingren), *Herba houttuyniae* (Yuxingcao), *Radix isatidis* (Banlangen), *Crassirhizomatis* (Mianmaguanzhong), *Herbapogostemonis* (Guanghuoxiang), *Rhizoma rhei* (Dahuang), *Rhizoma rhodiolae crenulatae* (Hongjingtian), and *Rhizoma glycyrrhizae* (Gancao), along with menthol and a traditional Chinese mineral medicine, *Gypsum fibrosum* (Shigao).

Uses

Modern pharmacological studies have shown that LQC also has antiviral, antibacterial, and anti-inflammatory activities.^[13]

Jinhua Qinggan Granule

It was first formulated during the 2009 H1N1 influenza pandemic.

Composition

Consisting of 12 herbal constituents such as honeysuckle, mint, licorice, jinyinhua (honeysuckle), zhebeimu, huangqin, niubangzi, and qinghao (sweet wormwood herb).

Uses

Reduce body temperature and detoxifies the lungs.^[14]

Xuebijing Injection

It was first formulated during the SARS epidemic in 2003.

Composition

Ingredients consisting of Honghua, Danggui, Chishao, Chuangxion, Danshen, and Danggui and other Chinese herbal extracts, and one of its main components is safflower yellow.

Uses

The main function is to detoxify and remove blood stasis.

Prevent excessive coagulation and the formation of thrombus.^[15]

HuaShi BaiDu Formula

HuaShi BaiDu is developed from national TCM by the China Academy of Chinese Medical Sciences.

Composition

Raw ephedra, almond, gypsum (decocted first), Licorice, Agastache Rugosa (later), Magnolia bark, Atractylodes rhizome, Tsaoko, Pinellia tuber, PoriaCocos, rhubarb (later), Astragalus root, Lepidium seed, and Red peony root.

Uses

Detoxifying and eliminating dampness, clearing away heat and relieving asthma, lowering turbidity, and relieving internal organs, benefiting qi, and dredging collaterals.^[16]

MADAGASCAR

COVID-Organics

On April 21, the President of Madagascar Andry Rajoelina launched a local herbal remedy that can prevent and cure novel coronavirus officially.^[17]

Composition

COVID-Organics is derived from *Artemisia* and other endemic medicinal plants, such as *Ravintsara*.

Artemisia annua contains artemisinin, which is the groundbreaking compound for its inhibitory efficacy on *Plasmodium falciparum*, the parasite that causes malaria. However, the extract has 53 compounds in addition to artemisinin which of these could have an inhibitory effect on SARS CoV-2's protease.^[18]

Uses

Effective against novel coronavirus by Global Scientific Community.^[19]

On October 03, 2020, they launched capsules containing extracts of *Artemisia* and *Ravintsara*, a local Malagasy plant, those who struggle to ingest the infusion can now take this CVO+ capsule.^[20]

THAILAND

Thailand has led to the peoples depend or rely on the traditional herbal formulation for contracting the virus, suppresses viral divisions despite a lack of scientific proof of the herbal formulation.

Fa Talai Jone Peoples claim that they boost immunity, viral cell divisions, ameliorate the lung inflammation from viral

infections, yet without scientific proof WHO does not mention anything regarding the use of this herbal formulation in the treatment of COVID. It was traditionally used to treat cold cough, sore throat, and viral respiratory infections and used as an anti-inflammatory, expectorant, and in the treatment of bronchitis.^[21]

Therapeutic Tea

Multicenter randomized controlled trial results from this study show that *Nigella sativa* and honey increase the clearance of virus and reduce the disease severity in COVID-19 patient.

Composition

Three blends are available currently with 25 herbs (strains of lemongrass, green tea, licorice, honeysuckle, broom creeper, neem, bitter apricot, and some other herbs, etc.) containing 31 active phytochemical constituents (such as *Strobilanthes cusia*, *Nigella sativa*, and *Aspalathus linearis*) which are present in these herbs are packed in tea bags.

Uses

Therapeutic tea is an herbal tea that has been used for prophylaxis and treating COVID-19 (mild to moderate).^[22]

NEPAL

- *Curcuma caesia*, *Zingiber officinale*, and *Allium sativum* these species are cultivated in almost all of rural Nepal. These herbal plants are listed by the Nepal Ministry of Health and Population Department of Ayurveda and Alternative Medicine, Kathmandu, as an alternative choice of medicine to boost immunity.
- Chemical constituents 8-Gingerol, 10-Gingerol from *Z. officinale* were active against COVID-19.
- COVID-19 patients might have cytokine storms and *C. caesia* has the capacity to block cytokine release.
- *A. sativum* mainly consists of sulfoxide, proteins, and polyphenols which are antiviral with immunostimulatory effect.
- *Tinospora cordifolia* has alkaloids, glycosides, lactones, and steroids with immunomodulatory roles and can treat fever, chronic diarrhea asthma.
- Citrus species encompass polysaccharides and polyphenolic compounds which enhance the immunity of the body.
- *Ocimum tenuiflorum* extract includes dihydrodieuganol and tulsinol (A, B, C, D, E, F, and G) that provides immunomodulatory and ACE II blocking properties to inhibit replication of coronavirus.
- *Phyllanthus emblica* possesses the antioxidant and anti-inflammatory property and to treat COVID-19.
- *Azadirachta indica* extracts consist of Nimocin, Nimbolin A, and Cycloartanols have shown potential to inhibit COVID-19.

Table 1: List of clinical trials for the treatment of COVID-19 in India^[27]

CTRI number	Type of trial	Type of study	Scientific title of study
CTRI/2020/07/026669	Interventional	Drug Unani Preventive	A clinical study to evaluate the efficacy of tablet of Aloe Vera gel, Mur Makki, and Sanna-e-Makki in the management of mild cases of confirmed COVID-19
CTRI/2020/07/026841	Interventional	Drug Ayurveda	Efficacy of Ayurvedic Preparations Haldi 30 drops as an Add medication to the standard of care in adult for mild-to-moderate COVID-19.
CTRI/2020/07/026925	Interventional	Drug Ayurveda Preventive	Clinical trials to evaluate prophylactic action of Twakadi herbal tea in police professionals working in COVID-19 pandemic
CTRI/2020/07/026530	Interventional	Ayurveda	A multi-centric, double-arm, open labeled, Phase II/III interventional study to assess the efficacy of composite Ayurvedic formulations for the treatment of COVID-19 infections.
CTRI/2020/07/026575	Interventional	Drug Ayurveda	Evaluation of Effect of Sahadevi (Vernonia cinerea) Powder in the symptomatic improvement of mild to moderate Covid-19.
CTRI/2020/07/026700	Interventional	Ayurveda Other (Specify)	Evaluate the safety, and efficacy of Ayurvedic formulation as an immunomodulator in minimizing the risk of COVID-19 infection or severe stage COVID in health care workers concerned in the care of patients with COVID
CTRI/2020/07/026355	Interventional	Ayurveda	Assessment of the efficacy of Ayush Kwath in the prevention of COVID-19 pandemic between persons residing in hotspot area
CTRI/2020/07/026705	Interventional	Drug Ayurveda	Evaluation of safety and efficacy of an AYUSH 64 as adjunct treatment to standard of care for the treatment of mild-to-moderate COVID-19 patients
CTRI/2020/06/02587	Interventional	Siddha	A randomized open-labeled clinical study to compare the effectiveness of Kabasurakudineer and Vitamin-C zinc supplementation in the management of asymptomatic SARS-CoV-2 patients
CTRI/2020/06/025856	Interventional	Siddha	An open clinical evaluation of selected Siddha regimen in expediting the management of COVID-19 – A randomized controlled study
CTRI/2020/06/025763	Interventional	Drug Siddha	A randomized clinical study to assess the complementary effect of Siddha formulations in enhancing the possibility of accelerated recovery in COVID-19 patients.
CTRI/2020/07/026673	Interventional	Siddha	Non-randomized clinical trial to evaluate the efficacy of siddha medicines NilavembuKudineer and KabasuraKudineer in the management of COVID-19 patients: An investigative study
CTRI/2020/05/025425	Interventional	Ayurveda Preventive	Assessment of the efficacy of an Ayurvedic intervention Chyawanprash in the prevention of COVID-19 pandemic between health-care personnel.
CTRI/2020/06/025525	Interventional	Drug Ayurveda Preventive	A prospective non-randomized open-label controlled interventional study on the effect of GuduchiGhanavati as a prophylactic measure among the population at high risk to SARS-CoV-2 exposure
CTRI/2020/05/025341	Interventional	Ayurveda Yoga and Naturopathy	Efficacy of KiratiktadiKwath and Ashwagandha Churna with yoga modalities in the management of COVID-19 patients.
CTRI/2020/05/025213	Interventional	Drug Ayurveda Preventive	Impact of Ayurvedic intervention (Guduchighanvati) in prevention of COVID-19 infection in containment areas of Himachal Pradesh – A community-based study
CTRI/2020/05/024986	Interventional	Homeopathy	Evaluation of Effectiveness of Arsenicum Album 30c in the prevention of COVID-19 in persons residing in hotspots of red zones in Delhi.
CTRI/2020/05/025166	Interventional	Drug Ayurveda Preventive	Observational Study of Ashwagandha tablet intake as a preventive measure in the pandemic of COVID-19 – An open-label, randomized, controlled, prospective, interventional, community-based clinical study on healthy subjects
CTRI/2020/07/026632	Interventional	Siddha	Effectiveness of Siddha Medicine in the treatment of COVID-19 Patients – A pilot study

(Contd...)

Table 1: (Continued)

CTRI number	Type of trial	Type of study	Scientific title of study
CTRI/2020/07/026674	Interventional	Ayurveda	Randomized clinical study of Ayurveda spice mix tablet for the treatment of COVID-19 in health-care personnel.
CTRI/2020/08/026980	Interventional	Ayurveda	Action management plan for COVID-19 based on Ayurveda decoctions, tablet, and Panchagavya.
CTRI/2020/11/029444	Interventional	Drug Ayurveda	A clinical trial to the study effect of Madhav Rasayan tablets in COVID-19 patients
CTRI/2020/09/027615	Interventional	Drug Homeopathy	Clinical study to assess the efficacy of Homeopathic preparation Arsenicum album as add-on therapy in treating hospitalized patients diagnosed with COVID-19.
CTRI/2020/09/027548	Interventional	Ayurveda Nutraceutical	Effects of Mulmina Mango as an adjunct to standard of care treatment on COVID-19-positive subjects undergoing treatment for COVID-19 in Hospital Quarantine
CTRI/2020/10/028230	Interventional	Ayurveda	A randomized comparative clinical trial to assess the efficacy of PippaliRasayana and Nagaradi Kashaya Ghana Vati combination as an adjuvant treatment with ICMR directed therapy in COVID-19-positive mildly symptomatic cases
CTRI/2020/10/028233	Interventional	Homeopathy	Homoeopathy medicines as add-on therapy in the management of COVID-19 cases at COVID care center in Kanyakumari district – A clinical trial
CTRI/2020/10/028414	Interventional	Drug Ayurveda	Study of Swarna Amalaki as an immunomodulator in COVID-19 patients.
CTRI/2020/11/029289	Interventional	Siddha	A prospective non-randomized single-arm, single-center clinical study to evaluate the effectiveness of Siddha medicine M V Kashayam in the management and treatment of COVID-19 patients

- *Mentha arvensis* possess eugenol, terpenes, and flavonoids which are good antioxidants and modulators of xenobiotic enzymes that help to inhibit COVID-19.
- *Cinnamomum verum* includes cinnamic acid, eugenol, caryophyllene possess antioxidant, and antiviral property help to inhibit COVID-19.^[23]

GERMAN

Researchers from Germany, Institute of Molecular Virology, ULM University Medical Center performed a new clinical study. This study reveals the effect of black chokeberry, green tea, elderberry juices, and pomegranate preventing SARS-CoV-2 viral infections in cells. A researcher found that some plant-derived products probably inactivate SARS-CoV-2. They have virucide property and diminish the viral load in the oral cavity. The *in vitro* test result indicates that these products kill the flu and SARS-CoV-2 viruses when incubated with viruses in the *in vitro* test.

Chokeberry inactivates 97% of the SARS-CoV-2 virus after 5 min, and pomegranate and green tea inactivate the virus up to 80%. Catechins is present in the green tea affects the viral particles, and then, they are combining to their host cells.^[24]

INDIA

Traditional medicines comprising herbs and oils could have a role in combatting COVID-19, in accordance with the new research. Traditional medicines are utilized by millions of individuals globally and being proved to diminish the effects of COVID-19. A comprehensive clinical management protocol on Yoga and Ayurveda had been issued by the Central Government of India that is to be accompanied by the Ayurvedic practitioners for the treatment of the COVID-19 patients.^[25] Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH) facilitates traditional healing treatments and listing of numerous practices for boosting the immune system responses.^[26] A complete list of clinical trial for the treatment of COVID-19 is shown in Table 1.

CONCLUSION

In this review article, we consistently outlined all the herbal plants and remedies indicated by the country based on their rules and guidelines. Around 70–80% of the global population depends on alternate and traditional herbal remedies.^[28] Because these herbal plants have low cost, less toxicity, and approximately found all across the country, it has the possibilities to strengthen the immunity to fighting

against the COVID-19 infection and plays a significant role to become healthy and fit India and globally.^[29] Furthermore, clinical trials are demanded to assess the safety and efficacy of traditional herbal remedies to produce clinical evidence. Subsequently, there are no accessible vaccines or prophylactic medicines for the treatment of COVID-19 infection. The integration of traditional herbal remedies into conventional remedies may exhibit an efficient rate in the improvement of symptoms related to COVID-19 and be an alternate method for the treatment of COVID-19 in the future.^[30]

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