

Efficacy of Ayurvedic “Amalaki Rasayan” for treating residual effects of viral infection COVID-19

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Abstract

Introduction: *Amalaki rasayan* is a unique formulation of *Embllica officinalis*, also commonly known as *amla*. *Amla* is a strong antioxidant and rejuvenating fruit, which is potentiated to formulate *Amalaki Rasayan*. This study elaborates on the preparation and standardization of the formulation. Its clinical trial in long COVID has been reported in this article in patients with long COVID having residual symptoms of the viral infection. **Methods:** *Amalaki Rasayan* was formulated and kept immersed in *bhasma rashi*, i.e., cow dung ash for 4 months for maturation. A single-arm open-label clinical trial of *Amalaki Rasayan* was conducted in 15 long-COVID patients for 30 days, after mild laxative treatment by *Haritakyadi Yoga*. **Results:** There was significant improvement in the WHO well-being score and reduction in symptoms, namely anorexia, fatigue, continuous headache, joint pain, anxiety, and dyspnea in post-COVID patients after 30 days of administration of *Amalaki Rasayan*. **Conclusion:** After administration of *Amalaki Rasayan*, the long-term residual effects after viral infection COVID-19 were significantly reduced and improvement in mood and well-being was noted. No adverse effects were noted.

Key words: Amalaki Rasayan, COVID-19, *Embllica officinalis*

INTRODUCTION

COVID-19 is an infectious disease caused by the coronavirus. COVID-19 is marked by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In the guidelines of NICE, two definitions of post-acute COVID-19 are given, namely ongoing symptomatic COVID-19 for people who still have symptoms between 4 and 12 weeks after the start of acute symptoms and post-COVID syndrome for people who still have symptoms for more than 12 weeks after the start of acute symptoms. This may last up to 1 year.^[1] Only 10.8% of patients had no manifestation once recovered from the disease. The most common symptom reported was fatigue, seen in almost 72.8%, followed by anxiety in 38%, joint pain in 31.4%, and continuous headache in 28.9%. Furthermore, critical manifestations such as diabetes mellitus, pulmonary fibrosis, stroke, and renal failure were reported by the subjects.^[1]

As per the *Ayurvedic* perspective, *Agnimandya* and *Dhatukshya* are evident in post-COVID conditions. With the help of *Rasayanchikitsa* (~Immunomodulating drugs), it is possible to treat post-COVID illness as well as prevent further complications by enhancing the function of Agni (~digestive system) and correcting the functions of Dhatu. Hence, *Rasayanchikitsa* may be useful in the post-COVID management of patients. The Ministry of AYUSH has also recommended *Rasayan* (immunity-boosting medicine) in post-COVID management.^[2]

The substance that invigorates a healthy person by producing the best quality of *Rasa*, *Rakta*, and other dhatus is called

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Rasayan also medicines which invigorate a healthy person are mostly aphrodisiacs and rejuvenators, also recommended for treating disease conditions.^[3] *Amalaki Rasayan* from *Charak Samhita, chikitsasthan prankamiya rasayanadhaya pada-2*, specifically indicated formulation for *pran vaha strotas dushti* (~ Disorders of respiratory system) and its associated symptoms such as *nidra* (~contributes to adequate sleep), reduces *tandra* (~dizziness), *shrama* (~fatigue), *klama* (~fatigue without exertion), *alasya, dourbalya* (~fatigue), and balances *tridoshas*, thus considering all these factors, we checked the efficacy of *Amalaki Rasayan* in post COVID patients.

Amalaki Rasayan from *Charak Chikitsasthan, prankamiya Rasayanadhyay 2-3*, has not studied previously in view of its detailed manufacturing and post-COVID usefulness. *Amalaki Rasayan* contains *Amalaki* [*Phyllanthus emblica* Linn.], *pippali* [*Piper longum* Linn.], *madhu* [honey], *ghrita* [cows' ghee], and *sharkara* [candy sugar]. A synergistic effect of all ingredients of *Amalaki Rasayan* resulted in *agnideepak, tridosha balancing, anulomak*, and *Rasayan* actions and does the nourishment of *Rasa dhatu* which further nourishes all the *dhatu*. Fruit of *Amalaki* (*Phyllanthus emblica* Linn.) has proven various activities such as antioxidant, cardioprotective activity, anti-diabetic, anti-cancer, anti-inflammatory and provides protection for the gastric tract and neurological.^[4] In this study formulation, firstly, *Amalaki choorna* (~powder) should be levigated with *Amalaki swaras* (~juice) 21 times, which will enhance potency and help in reducing the drug dose. The previous study on *Amalaki Rasayan* reported AR 7 (*Amalaki* powder is levigated with *Amalaki* juice 7 times) and AR 21 (*Amalaki* powder is levigated with *Amalaki* juice 21 times) both of which possess significant immunostimulant and cytoprotective activity. However, AR 21 shows better activity toward immunostimulant and cytoprotective.^[5]

Pippali (*Piper longum* Linn.) showed anti-inflammatory,^[6] immunomodulatory,^[7] cardioprotective,^[8] anti-diabetic activity,^[9] and anti-diabetic and hyperlipidemic activity.^[10] Piperine is a major alkaloid present in *Piper longum*, known for a bioenhance.^[11] Honey has been investigated for different pharmacological activities and its uses in different clinical conditions such as anti-oxidant, anti-inflammatory, anti-microbial, anti-bacterial, and anti-viral. Furthermore, honey is beneficial for wound healing and cough reducing properties.^[12] *Goghrita* is useful in improving functions of *dhee* (~ memory), *smriti* (~intellect), *medha* (~intelligence), *agnivardhak* (~ increases digestive power), *balavardhak* (~strength) and it can be administered in children's as well as in old age people. Cow's ghee is rich in Vitamins A, D, E, K, and omega 3, 9 fatty acids. Small chain fatty saturated acids (SFA) such as butyric acid, caproic acid, and caprylic acid. Medium-chain fatty acid includes capric and myristic acid.^[13] All the notorious active principles present in cow's ghee help in maintain general well-being of individuals. Thus, the synergistic effect of all ingredients of *Amalaki Rasayan* is expected for beneficial in treating post-COVID-19 symptoms.

Thus, the present study was designed to prepare and standardize *Amalaki Rasayan* and further its efficacy in post-COVID-19 management using the WHO well-being index scale, clinical signs, and symptoms. The main assessment criteria were the WHO well-being scale and the other symptoms. We administered *Amalaki Rasayan* by the method of *vatatapika Rasayan* instead of *kutipraveshik Rasayan*. It is very essential to undergo *samshodhan* before to undergo *Rasayan* by *Panchakarma*. (*snehan, swedan, vaman, virechan, etc.*) but whole *panchakarma* is not possible due to stressful life and job timing, etc. However, *koshthashudhi* is necessary. Hence, *Haritakyadi Yoga* was given for *koshthashuddhi*.

MATERIALS AND METHODS

A. *Preparation of Amalaki Rasayan*. *Amalaki Rasayan* was prepared using the classical reference of *Charaksamhita Chikitsasthan, Pranakamiya rasayan Adhyaya, verse 8*.^[14] *Amalaki Rasayan* contains following ingredients with specific ratios. Table 1 describes the ingredients of *Amalaki Rasayan*.

Methodology

All the raw ingredients of *Amalaki Rasayan* were authenticated in the quality control laboratory. *Amalaki powder* was levigated with *Amalaki juice* for 21 days using a wet grinder. Each day fresh *Amalaki* juice was prepared. All the details of during 21 times of *Bhavana* process (~levigation process) were recorded. The 21 levigated mixture was allowed to sundry; then, it was ground to form powder. Honey, cows' ghee, *Piper longum* Linn., and candy sugar were added to the 21-day levigated dried mixture with respective quantities, stirred to attain homogeneous consistency. This entire mixture was transferred into the ghee-smeared glass jar, was tightly sealed with the fuller's earth and cloth, and allowed to dry. Then, the glass jar was kept in *bhasma rashi* (~cow dung ash) for the next 4 months without disturbing. After 4 months, the glass jar was removed outside from the cow dung ash. The final product was stored in clean, washed, and dried bottles, providing 1/3 vacant space in the bottles. Labeling and packaging were done as per the Drugs and Cosmetics Rules, 1945, Part – XVII, Rule 1619. The detailed process of manufacturing is represented in Figure 1.

The *Haritakyadichoorna* (~powder) was prepared with the classical reference of *Charak Samhita, Chikitsasthan, AbhayaamlakirasayanAdhyay* (verse 24). The *Haritakyadi* powder contains *Haritaki* (*Terminalia chebulla* Linn.), *saindhav* (rock salt), *Amalaki* (*Phyllanthus emblica* Linn.), *Jaggery*, *Vacha* (*Acorus calamus* Linn.), *Vidang* (*Embiliaribes* Linn.), *Haridra* (*Curcuma longa* Linn.), *Pippali* (*piper longum* Linn.), *Vishwabhashaj* (*Zingiber officinale*) powders in equal

amounts. It was sieved through 85 # mesh to obtain fine powder, was packed in airtight bag, and labeled as per Drugs and Cosmetics Rules, 1945 Part – XVII, Rule 1619.

B. Analytical study: *Amalaki Rasayan* was analyzed for organoleptic tests and physicochemical parameters, thin layer chromatography (TLC), and high-performance TLC (HPTLC) for both times, i.e., before keeping in *bhasma rashi* (~cow dung ash) and after keeping in cow dung ash at the in-house laboratory.

Organoleptic and physicochemical evaluation of *Amalaki Rasayan* before keeping in cow dung ash and after 4 months, keeping in cow dung ash, is depicted in Tables 2 and 3.

The samples were subjected to HP-TLC. Higher percentage of gallic acid and piperine was noted after 4 months of keeping in *bhasma rashi*. HPTLC profiles, i.e., before keeping in cow dung ash and after 4 months keeping in cow dung ash, are provided in Figure 2a and b.

Table 1: Ingredients with proportion of *Amalaki Rasayan* as per Charakasamhita Rasayan Adhyaya

Ingredients	Scientific name	Parts to be used	Quantity
<i>Amalaki</i>	<i>Embolica officinalis</i> Linn.	Fruit powder and fruit juice	<i>Amalaki powder</i> 1280 g Fresh <i>Amalaki</i> juice 6300 mL
<i>Madhu</i>	Honey	-	1280 g
<i>Goghruta</i>	Cow ghee	-	1280 g
<i>Pippali</i>	<i>Piper longum</i> Linn.	Fruit powder	160 g
<i>Khanda Sharkara</i>	Candy sugar	Powder	320 g

Table 2: Organoleptic parameters of *Amalaki Rasayan* before and 4 months after keeping in *bhasma rashi*

Organoleptic test	<i>Amalaki Rasayan</i> before keeping in <i>bhasma rashi</i>	<i>Amalaki Rasayan</i> after keeping 4 months in <i>bhasma rashi</i>
Sparsh [touch]	Mrudu	Mrudu
Rupa [color and appearance]	Blackish brown, semisolid	Blackish brown, semisolid
Rasa [taste]	Sour	Sour astringent
Gandha [odor]	Strong, characteristic, like <i>Embolica officinalis</i>	Strong, characteristic, <i>Embolica officinalis</i>

METHODS- Pharmaceutical study



Figure 1: Preparation of *Amalaki Rasayan*

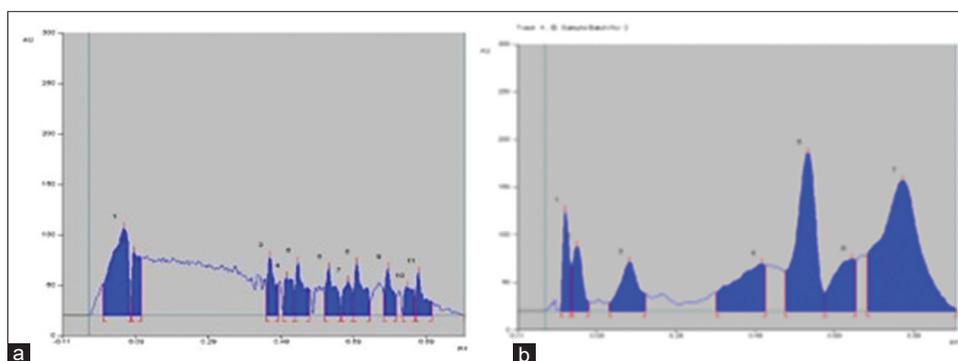


Figure 2: (a) High-performance thin layer chromatography (HPTLC) of *Amalaki Rasayan* immediately after preparation, (b) HPTLC of *Amalaki Rasayan* after keeping in *dhanyarashi* for 4 months

Table 3: Physicochemical parameters of *Amalaki Rasayan*; before and 4 months after keeping in *bhasma rashi*

Quality control tests	<i>Amalaki Rasayan</i> (before keeping in <i>bhasma rashi</i>)	<i>Amalaki Rasayan</i> (after keeping in <i>bhasma rashi</i>)
pH	2.96	3
Water-soluble extractive	40.8%	44.8%
Alcohol soluble extractive	56%	52%
Ash value	2%	2%

Amalaki Rasayan was also analyzed for microbial load and vitamin C. The microbial load in *Amalaki Rasayan* was found below permissible limits.

C. Clinical study: The study was approved by the Institutional Human Ethics Committee of BVDU College of Ayurved Pune. The trial was registered with the Clinical Trial Registry of India (CTRI/2022/05/042410). It was a single-arm open-label uncontrolled clinical trial conducted at Bharati Ayurved Hospital, Katraj, Pune. Being an exploratory clinical trial, the sample size was kept.^[15]

Inclusion Criteria

Long COVID-19 patients have symptoms of fatigue, anorexia, anxiety, continuous headache, joint pain, dyspnea in the long COVID-19 span and age group between 18 and 70 years of age.

Exclusion Criteria

Long COVID-19 patients having any critical medical emergency, including cardiac diseases and K/C/O asthma, COPD, and ARDS patients, were excluded. Critical long COVID-19 complications such as stroke, renal failure,

myocarditis, mucormycosis, uncontrolled DM, and hypertension were not selected for the clinical trial.

The patients suffering from signs and symptoms of fatigue, anorexia, joint pain, continuous headache, anxiety, and dyspnea in post-COVID-19 span were registered from OPD of the Kayachikitsa Department in Bharati Ayurved Hospital, Katraj, Pune, irrespective of age, sex, caste, religion, etc. Each patient was examined, and data were recorded in a clinical case format, the WHO well-being scale, long COVID-19 signs and symptoms. Informed written consent was taken from each individual before the study. Five gram of Haritakyadi Yoga was administered with lukewarm water for 3, 5, 7 days according to *mrudu*, *madhyam*, and *Krurkoshtha* (~bowel habits). After *koshthashudhi*, 10 g of *Amalaki Rasayan* for the next 30 days was administered in *Rasayan kala* (~ early morning on an empty stomach). The follow-up was taken on 0th, 15th, 31th day after receiving the *Amalaki Rasayan*. On the day 31st, the assessment was done using the WHO well-being scale, clinical signs, and symptoms. The CONSORT flow diagram of the study is provided in Figure 3.

RESULTS

The WHO well-being scale and clinical sign symptoms were used for assessment. The Wilcoxon signed-rank test was used to assess efficacy. *Amalaki Rasayan* was found to be effective in reducing symptoms, namely anorexia, fatigue, continuous headache, joint pain, anxiety, and dyspnea in post-COVID-19 patients. There was a significant improvement seen WHO well-being score in 30 days of treatment with *Amalaki Rasayan*. No adverse drug reaction was documented throughout the entire study period.

DISCUSSION

In post-COVID syndrome, people still have symptoms for more than 12 weeks after an acute viral infection. This may last up to 1 year. Post-COVID is an assorted condition

CONSORT FLOW CHART

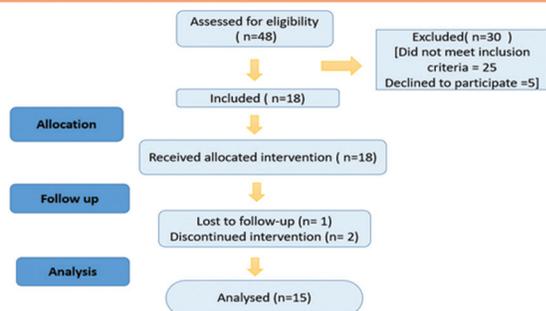


Figure 3: CONSORT chart of the clinical trial of *Amalaki Rasayan*

that contains multiple factors such as persistent SARS-CoV-2, long-term tissue damage, inflammatory diseases, immunosuppression, and gut dysbiosis. All these etiological phenomena can be responsible for different symptoms of post-COVID.^[16]

From an Ayurvedic aspects, *Agnimandya* and *Dhatukshyaavastha* are evident in post-COVID conditions and other viral respiratory infections. Post-COVID-19 symptoms include *shrama* (~fatigue) and *klama* (~fatigue without exertion), *aruchi* (~anorexia), *sandhishoola* (~joint pain), *shirashoola* (~headache), *shwas* (~dyspnea), anxiety and it shows the contribution of *prana*, *rasa*, *rakta*, *mansa*, *asthi*, *majjavahastrotodushiti* with the vitiation of *tridoshas*. The *Amalaki Rasayan* from *Charak Chikitsasthan*, *prankamiya Rasayanadhyay* is specifically indicated for *pranvhastrotasdushiti* and associated symptoms such as *shrama* (~fatigue), *klama* (fatigue without exertion), *dourbalya* (~weakness), balances *tridoshas*, *agnideepak*, enhances *prabha*, *varna*, *swar*. It concludes that the synergistic effect of *Amalaki Rasayan* from *Charak Samhita* may be effective in treating post-COVID patients. Furthermore, none of the studies was documented in the pharmaceutical study of *Amalaki Rasayan* as well as in the management of post-COVID-19 ailments. Hence, it was proposed that a pharmaceutical study, analytical study, and clinical trial of *Amalaki Rasayan* were conducted on patients of post-COVID patients.

The study formulation was mentioned in *Charakchikitsasthan*, *Prakriti Sutrasyanadhyay*, verse 8 mentioned under the name of *Amalaki choorna*. A finished formulation does not exist in proper *Churna form* but it is in *semisolid awaleha* form. But also, the same formulation is described in *Bharat Bhaishjya Ratnakar* under the name of *Amalaki Rasayan*,^[17] and it is a semi-solid formulation; hence, we have also quoted as *Amalaki Rasayan*. During formulation preparation, the levigation process was carried out in a wet grinder instead of 21 nights of soaking of *Amalaki choorna* in *Amalaki swaras*. This soaking may lead to fungal growth in the formulation and using a wet grinder was more convenient for 21 days of levigation. The formulation has been advised to be kept in *bhasma rashi*, which may maintain a constant temperature in it and avoid environmental contamination. Furthermore,

here, *Kaal sanskar* may enhance the potency of *Amalaki Rasayan*. In organoleptic tests, *Amla rasa* was dominantly expressed before keeping in *bhasma rashi*, and after 4 months of keeping in *bhasmarashi*, *Kashaya rasa* was also observed along with *amala rasa*. This may be due to the 4 months of *kaal sanskar* of *Amalaki Rasayan*. HP-TLC profile revealed that the percentage of *gallic acid* and *piperine* was increased after 4 months of keeping in *bhasma rashi*. This can be due to the extraction of all active components in the *Amalaki Rasayan*. Then, the final finished formulation was subjected to microbial load using the API parameter, and it was found below the permissible limit of total plate count. A significant improvement was noted in symptoms of post-COVID-19 and the WHO well-being scale after the treatment of *Amalaki Rasayan*. This is attributed due to the *agnideepak*, *tridoshahar*, and *anulomak*, *Rasayan* properties of *Amalaki Rasayan* which helped in diminishing the *Aam* from the body by enhancing the function of *agni* and correcting *rasavahadusthi*. *Rasa dhatu* which further nourishes all the *dhatu*. The fruits of *Amalaki* (*Phyllanthus emblica* Linn.) have been known for immunomodulatory activity, antioxidant activity, cardioprotective, hepatoprotective, and anti-inflammatory activity.^[18] *Pippali* (*Piper longum*) is a known bio-enhancer drug^[11] also^[18] it also showed significant anti-inflammatory,^[6] anti-viral and immunomodulatory activity,^[19] cardioprotective,^[8] anti-diabetic, and anti-hyperlipidemic activities.^[10] Recent studies on honey have proven for its anti-inflammatory, anti-bacterial, and antimicrobial activity. In another study carried out by Olaitan *et al.* suggests, honey is a reservoir and repressing agent for microorganisms. Cows' ghee is lipophilic in nature which easily facilitates the entry of formulation into the cells as well as improves general well-being. All the synergistic effects of the ingredients of *Amalaki Rasayan* may show effectiveness in long COVID syndrome.

CONCLUSION

Importance of *Bhavana* (~levigation process) and *Kalsanskar* was noted by analyzing the *Amalaki Rasayan*, before and after 4 months of maturation by keeping in *bhasmarashi* (~cow dung ash). It is noted that the percentage of gallic acid and piperine increased after *keeping* the formulation in *bhasma rashi*. *Amalaki Rasayan* proved to be effective in treating post-COVID-19 symptoms such as fatigue, anorexia, joint pain, continuous headache, anxiety, and dyspnea in this single-arm open-label clinical trial. Significant improvement was noted in the quality of life in the post-COVID-19 patients with an increased WHO well-being score. No adverse drug reactions were noted.

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AUTHORSHIP STATEMENT

All authors contributed equally to planning and conduction of this research work. Author 1 - Conceptualization, methodology, analysis, writing, and review. Author 2 - Conceptualization, methodology, analysis, writing, and review. Author 3 - Conceptualization, methodology.

DATA AVAILABILITY STATEMENT

All the data utilized for this manuscript can be made available by the authors upon reasonable request.

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