

**Original article**

**ADRs (Adverse Drug Reactions) related to ayurvedic medicine used in COVID-19**

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**Abstract:**

**Background:** Adverse Drug Reaction (ADR) is a response to a drug which is noxious and unintended, and which occurs at therapeutic doses. Due to a lack of systematic documentation regarding the occurrence of ADR and other issues to the safety of Ayurvedic medicines, concern about the traditional medical system has recently been increased. This is seen by a rise in safety reports and misunderstandings, especially in the recent pandemic. **Objective:** To monitor and analyse the suspected ADR to Ayurvedic medicines used in COVID-19. **Materials and Methods:** ADR monitoring data was collected through spontaneous and intensive method for a span of 2-year (April 2020 to April 2022) during the peak days of COVID-19 from the IPvCC of the National Institute of Ayurveda, Jaipur, India. The IPvCC Program is governed by NPvCC under the supervision of Ministry of AYUSH, Govt. of India, New Delhi. NPvCC is ultimately responsible to monitor and recommend regulatory interventions on the generated national ADR data. **Result:** In a span of two-year, 142 adverse drug events were reported out of which 17 were confirmed as ADR due to suspected Ayurvedic drugs. **Conclusion:** Overall review demonstrated that Ayurveda has traditionally been placed a strong emphasis on treatments that aim to heal the underlying illness while preventing the development of new illnesses.

**Keywords:** Pharmacovigilance; Suspected ADR; Cap. Ayush 64; *Sanshamni vati*.

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**Introduction:**

Coronavirus disease (COVID-19) is a contagious illness caused by the SARS-CoV-2 virus. This virus was previously unknown to medical science.<sup>1</sup> The first case of COVID-19 in India was reported on January 30, 2020, and it quickly spread throughout the country.<sup>2</sup> The severity of COVID-19 had brought attention to the challenges facing the healthcare system, the same rapid disease outbreaks called for the fusion of traditional knowledge systems and modern medicine. The World Health Organisation

(WHO) was constantly monitoring the disease pandemic and updating the information available regarding its spread, mortality, and morbidity.<sup>3</sup>

From the *Ayurvedic* point of view, COVID-19 comes under *janapadodhwamsa vikara* (epidemic disease). The concept of an epidemic diseases is described in *Charaka Samhita*.<sup>4</sup> With recommended guidelines of AYUSH Ministry, Govt. of India, the use of Ayurvedic medicine for Covid-19 was increased. However, the widespread misconception about herbal medications is that they are fully risk-free.<sup>5</sup> This

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delusion has encouraged widespread self-medication worldwide, frequently with unfavorable outcomes and side-effect consequences. Consumers may have negative repercussions including adverse drug reactions (ADRs) and drug-drug interactions if they are not informed about how to use medicine properly. In order to protect the public's health, practitioners and healthcare professionals in ASU&H hospitals must now use extreme caution when it comes to drug safety monitoring.<sup>6</sup> Since pharmacovigilance is all about the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other possible drug related problem<sup>7</sup> and ADR are the reaction that may be due to the drug itself or one of its metabolites, from an interaction between two or more drugs or between a drug and food. According to WHO "ADR is defined as a response to a drug that is noxious and unintended, and that occurs at doses normally used in human for the prophylaxis's, diagnosis or therapy of disease or for the modification of physiological function"<sup>6,7</sup>. Suspected ADR means that while a causal relationship in the individual case has not been proven, a relationship is initially assumed to exist between the medicine taken and the symptoms or diagnosis.<sup>7</sup>

### Material and Methods:

The Ministry of AYUSH, Govt. of India, began the clinical trials of Ayurvedic medicines for treating and preventing the novel coronavirus that causes COVID-19. The clinical trials of Ayush medicines for COVID-19 was a joint initiative of three organisations viz. the Ministry of AYUSH, the Ministry of Health & Family Welfare and Council of Scientific and Industrial Research (CSIR) with technical support of Indian Council of Medical Research (ICMR).<sup>8,9,10</sup> Ayurvedic medicines such as *Ashwagandha*, *Yashtimadhu*, *Guduchi Pippali*, *Guduchi Ghanavati* (Samshamani Vati), Ayush kwath, and a poly herbal formulation (Ayush-64) are being used in the clinical trials involving health workers and those working in COVID-19 high-risk areas.<sup>11,12</sup>

In the current study, ADR monitoring data was collected through spontaneous and intensive method for a span of 2-year (April 2020 to April 2022) during the peak days of COVID-19 from the Intermediary Pharmacovigilance Coordination Centre (IPvCC) of the National Institute of Ayurveda, Jaipur, India. The IPvCC Program is governed by National Pharmacovigilance Coordination Centre (NPvCC) under the supervision of Ministry of AYUSH, Govt.

of India, New Delhi. NPvCC is ultimately responsible to monitor and recommend regulatory interventions on the generated national ADR data.<sup>13,14</sup>

### Result:

The incidence and characteristics of ADR to *Ayurvedic* medication have been recorded in the current data during the period of COVID-19. This would assist in creating a number of measures to increase pharmacovigilance in Ayurveda. One year's worth of 142 reported adverse medication reactions, resulted in 17 identified as suspected drug-related ADRs (Table 1). These cases involve three ADRs reported from AYUSH-64 with complaints of headache, nausea, and dizziness. One ADR with complaints of elation, flatulence, and headache was recorded from *Samsamni vati*. Four ADRs were reported from *Ashwagandha Churna* with the typical complaints of headache, bloating in the abdomen, and loose motion. One ADR recorded from *Chyavanprash*, Five ADRs reported from homemade decoction, and *Ayush kwath*. Two ADRs reported from *yashtimadhu churna*. The suspected drug ADR was assessed using contemporary criteria.

### Discussion:

It has been noted that only a small number of Ayurvedic medications are used by patients as over the counter (OTC) medications. In a variety of health care facilities, these OTCs are offered for sale as either herbal medications or herbal products. Some adverse events have also been recorded as a result of insufficient regulatory measures, mostly uncontrolled distribution methods, such as mail order or online sales, poor quality control systems, and incorrect administration.<sup>15</sup>

Researchers from reputable national research organisations have discovered that the polyherbal formulation AYUSH-64 can be used as a supplemental treatment for asymptomatic, mild and moderate Covid-19 infection.<sup>16</sup> At the National Institute of Nutrition in Hyderabad (NIN-ICMR), a pre-clinical investigation was also carried out to assess the immune-modulatory potential and safety/toxicity of the AYUSH Kwatha formulation. The Ministry has conducted nationwide community-based studies through its Research Councils (CCRAS) and instructed these National Institutes for mass distribution of AYUSH-64 to asymptomatic, mild to moderate COVID-19 patients in home isolation during the second COVID-19 outbreak in India based on the potential leads identified through

various studies.

A clinical trial comparing the efficacy/safety of *Ashwagandha* with Hydroxychloroquine Sulphate (HCQ) for COVID-19 Prophylaxis in high-risk healthcare workers showed that *Ashwagandha* is non-inferior to Hydroxychloroquine in terms of prophylactic effect against COVID-19. Further, it has a superior safety profile as significantly less adverse events were reported in the *Ashwagandha* group compared to HCQ group.

As seen in clinical experiments conducted during the COVID-19 pandemic, the formulation known as *Guduchi* Ghana vati or *Samshamani* Vati, which is made from aqueous extracts of the stem of *Tinospora cordifolia*, had a favourable impact on people's immune system and general well-being. Most study participants consumed *guduchi* ghan vati. This satisfactory drug compliance may depend on the dose, dosage form, and palatability of the formula. Gastrointestinal issues were infrequently observed as ADR/AE in patients and were managed with dietary advice, modifications to medication administration schedules, etc. No severe ADRs or serious AEs that necessitated hospitalisation occurred with *guduchi*.

The results support the prophylaxis potential of *Chyawanprash* as one of the preventive remedies for COVID-19. It has been found effective and safe among the high-risk health care workers and apparently healthy individuals in reducing the incidence of COVID-19.

Pharmacovigilance program for Ayush medicine is coordinated by NPvCC under the supervision of Ministry of AYUSH, Govt. of India, New Delhi that monitors the ADRs of traditional medicine and recommend regulatory interventions based on the generated ADR data. NPvCC has also launched specific suspected ADR Reporting Form for Drugs

used in Covid-19.

The current understanding of COVID-19 indicates that good immune status is vital for prevention and safeguard from disease progression. Ayush interventions can certainly play a pivotal role in the modulation of immune system thereby providing prophylaxis against COVID-19 and prevention of disease progression in COVID-19 patients.

#### **Conclusion:**

Based on the study outcomes of the clinical trials undertaken during COVID-19 pandemic, these Ayush medicines are proposed for COVID-19 prophylaxis and management. Further, the safety of these interventions is not an issue as such as these interventions are routinely used in the clinical practice since ages. Moreover, there is wide-spread acceptance regarding the effectiveness and safety of Ayush interventions in common ailments among the masses. When a drug is taken in proper form, dose, time and with specific *Anupana*, then there is less chance of causing any ADR.<sup>16</sup>

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**Authors' contribution:** The first-three authors collected the data of Ayurvedic medicine. The fourth author contributed in manuscript writing

**Data gathering and idea owner of this study:** The data was gathered by the first three authors

**Study design:** The study was designed by the fourth author.

**Data gathering:** The first-three authors

**Writing and submitting manuscript:** By all authors

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**Table 1: Data related to ADR**

| ADR Code Number    | Name of (IPVC) | Diagnosis                        | Date and time of initial observation | Description of A.D.R.  | any chronic disorders                         | List of all ASU & H Drugs used by the Patient in past one month.  | List of other drugs used by the patient during the period of one month:                            | Name of the Suspected drug for causing ADR            | Outcome of the suspected adverse reaction: Recovered/ Not Recovered/ Unknown/ Fatal | ADR: Severe: Yes / No. | Date of Reporting |
|--------------------|----------------|----------------------------------|--------------------------------------|--|---|---|--|---|---|------------------------|-------------------|
| AY-NIA/011/13/2019 | NIA Jaipur     | Covid 19                         | 30-06-20                             | Vomiting and difficulty in breathing   | Diabetes                                      | Ayush-64  | Tab. Metformin   | Ayush-64  | Fatal   | Yes                    | 05-08-20          |
| AY-NIA/011/14/2019 | NIA Jaipur     | Covid 19                         | 28-07-20                             | Vomiting, Headache, Dizziness  | NA  | Ayush-64  | NA   | Ayush-64  | Not Recovered   | No                     | 03-08-20          |
| AY-NIA/002/1/2020  | NIA Jaipur     | Kas-Pratishyay                   | 21-11-20                             | Pustules form acne vulgaris on both cheeks ( Mukhdushika)  | NA  | Churna Yashtimadhu , Churna Sitopaladi, Tab.Yashtimadhu, Tab.Tribhuvankirti   | Tab.Thyronorm  | Churna. Yashtimadhu, Tab. Yashtimadhu, Tribhuvankirti | NA  | NA                     | 10-12-20          |
| AY-NIA/002/03/2021 | NIA Jaipur     | Aamvata                          | 22.01.21 morning                     | Patient had on & off swelling on upper lip and mild itching on face in the evening every day and subsided on next morning.   | Rheumatoid Arthritis                          | Simhanad Guggul, Tribhuvankirti ras, Cap. Ayush 64, Lagusushokhar, Mahasudarshan Ghan vati, Punamava mandur, Sanjivani vati | tab. Naproxen , Tab. Folvite   | Cap. AYUSH 64 , Sanjivani vati                        | Recovered   | No                     | 23-01-21          |
| AY-NIA/002/05/2021 | NIA Jaipur     | Parikartika(Anal Fissure)        | 02.01.21                             | Mouth ulcers, stomatitis, gingivitis, burning sensation in abdomen, loose motions, fissures, burning pain in anus, increased mental irritations  | Thyroidism                                    | Ayush kwath and other spices like lavang, ela, etc.   | Tab. Thyronorm   | Ayush Kwath and other spices like lavang, ela etc.    | Recovered   | No                     | 02.01.21          |
| AY-NIA/002/06/2021 | NIA Jaipur     | Shool                            | 02.01.21                             | Patient suffering bleeding per rectum, fever, burning sensation with pain in abdomen, on & off sticky-loose motions, burning pain in anus.   | NA  | Ayush Kwath   | NA   | Ayush kwath   | Recovered   | No                     | 02.01.21          |
| NIA/002/13/2021    | NIA Jaipur     | Shoth                            | 20.02.21 morning                     | Medicines were prescribed for oedema (Shoth) on feet and all over the body in niram avastha. Patient observed that heaviness and oedema all over the body was increased after consuming the medicines. | NA  | 1. Sitopaladi Churna 2. Yashtimadhu Churna  | NA   | Sitopaladi Churna, Yashtimadhu Churna                 | Gradually   | No                     | 20.02.21          |
| NIA/002/14/2021    | NIA Jaipur     | Vam Pakshaghat ( Lt. Hemiplegia) | 22.02.21 morning                     | Patient had 6-7 episodes of loose motion for 3-4 days with pain in abdomen, weakness, body ache.   | Cardiac, Diabetes, Lt. Hemiplegia, Thyroidism | Ashwagandha Churna  | 1. Tab. Stovras 2. Tab. Clopidogrel 3. Tab. Atrin 4.Tab. Thyronorm 5.Tab. Azulix- MF 6.Tab. Dilzem | Ashwagandha Churna                                    | Recovered   | No                     | 04.03.21          |

| ADR Code Number    | Name of (IPvC) | Diagnosis                          | Date and time of initial observation | Description of A.D.R.  | any chronic disorders | List of all ASU & H Drugs used by the Patient in past one month.                 | List of other drugs used by the patient during the period of one month:       | Name of the Suspected drug for causing ADR  | Outcome of the suspected adverse reaction: Recovered/ Not Recovered/ Unknown/ Fatal | ADR: Severe: Yes / No. | Date of Reporting |
|--------------------|----------------|------------------------------------|--------------------------------------|--|-----------------------|--|---|---|---|------------------------|-------------------|
| NIA/007/03/2021    | NIA Jaipur     | Prinic 8 months 11 days ( Anariva) | 05.04.21 at 11:00 Am                 | Patient taken advised LA from 20.02.2021 to 30.03.2021. on 30.03.2021, noticed black spot & itching over abdomen hence patient stopped kailash jeevan from 30.03.2021  | No                    | 1. Kailash Jeevan  | 1. Tb. Primical<br>2. Tb. Folimex TD<br>3. Stavari Yasti<br>4. Protein Powder | Kailash Jeevan Multipurpose ayurvedic Cream | Recovered   | No                     | 06.04.21          |
| NIA/002/22/2021    | NIA Jaipur     | Manyagat Vaat                      | 15.05.21 afternoon                   | Patient has been coming to the OPD for Vatyadhi for the last one year. Yograj Guggul, Rasnasaptak kwath, laghu sutshekhhar were prescribed between 17th April to 1st May. Dhatri loha, Tab. Ashwagandha, Yograj Guggul were prescribed on 1st May for 14 days. 3 to 4 days after consuming the medicine patient complained giddiness and heaviness in the body.  | NA                    | 1. Yograj Guggul, 2. Rasnasaptak kwath 3. Ashwagandha churna vati 4. Dhatri loha | NA  | Ashwagandha churna Vati                     | Recovered   | No                     | 22.05.21          |
| AY-NIA/002/27/2021 | NIA Jaipur     | Madhumeha (diabetes)               | 12th July 2021 in the morning.       | Patient is known case of Madhumeha (diabetes) with history of covid-positive - He has been coming to the OPD for 7 months came for next follow-up on 4th June 2021 - tab. Nishamalaki and tab. ashwagandha churna were prescribed - from next morning he observed foul smell in urine - medicine continued for one month, still foul smell urine was present - after completed the course, the foul smell stopped coming from the urine- patient reported to the physician on 12th July 2021- duration-tab. Nishamalki from 23th Jan 2021 (6 months), Tab. Ashwagandha churna from 4th June 2021 (one month) | Diabetes              | 1. Tab. Nishamalaki<br>2. Tab. Ashwagandha churna                                | Cap. Zinco vit  | Tab. Ashwagandha churna                     | Recovered   | No                     | 01.08.21          |

| ADR Code Number    | Name of (IPvC) | Diagnosis         | Date and time of initial observation | Description of A.D.R.  | any chronic disorders                  | List of all ASU & H Drugs used by the Patient in past one month.                     | List of other drugs used by the patient during the period of one month:        | Name of the Suspected drug for causing ADR   | Outcome of the suspected adverse reaction: Recovered/ Not Recovered/ Unknown/ Fatal | ADR: Severe: Yes / No. | Date of Reporting |
|--------------------|----------------|-------------------|--------------------------------------|--|--|--|--|--|---|------------------------|-------------------|
| AY-NIA/002/30/2021 | NIA Jaipur     | Vibandha          | 23rd Aug 2021 in afternoon.          | A male patient k/c/o hypertension, diabetes & hyperlipidaemia came to general OPD on 23rd August 2021 for constipation, indigestion and abdominal bloating - reported that he consumed homemade decoction from Nov.2020 to April 2021 (approx.5-6 months) made by Giloy, turmeric and jaggery - he stopped to consume the decoction in the past 3 months (May to July 2021) - after discontinuation of decoction he suffering from constipation, indigestion and bloating .  | Diabetes, Hypertension                 | NA   | 1.Tb. Ecosprin<br>2.Tb. Plavix<br>3.Tb. Azor<br>4.Tb. Losar H<br>5.Tb. PAN     | Homemade decoction made by Giloy, Turmeric, Jaggery - 20 ml thrice in a week for 5-6 months. | Recovered   | No                     | 06.09.21          |
| AY-NIA/002/34/2021 | NIA Jaipur     | Ca. Sigmoid Colon | 6th Sept 2021 in the morning.        | A female patient k/c/o Ca. Sigmoid Colon has been coming to the cancer OPD since 2014 - she came to follow-up on 9th August 2021 in the morning for flatulence, hyperacidity, heaviness in lower limb, giddiness, headache - she was administered Ashwagandha churna, Nishamalaki, Chitrakadi vati , Syp. Vasaco for 30 days - in 9-10 days after consuming the medicines, she suffered from pain and heaviness in head (Parietal) with abdominal bloating - she continued all medicines but stopped Ashwagandha churna after 15 days - reaction abated after discontinued the Ashwagandha Churna. | Diabetes, Hypertension, Hypothyroidism | 1. Ashwagandha Churna<br>2. Tab. Nishamalaki<br>3. Chitrakadi Vati<br>4. Syp. Vasaco | 1. Tb. Neurobion forte<br>2. Tb. Telma<br>3. Tb. Altroxin<br>4. Tb. Tendia - M | Ashwagandha Churna   | Recovered   | No                     | 23.09.21          |



| ADR Code Number    | Name of (IPvC) | Diagnosis     | Date and time of initial observation | Description of A.D.R.   | any chronic disorders | List of all ASU & H Drugs used by the Patient in past one month.  | List of other drugs used by the patient during the period of one month: | Name of the Suspected drug for causing ADR   | Outcome of the suspected adverse reaction: Recovered/ Not Recovered/ Unknown/ Fatal | ADR: Severe: Yes / No. | Date of Reporting |
|--------------------|----------------|---------------|--------------------------------------|---|-----------------------|---|---|--|---|------------------------|-------------------|
| AY-NIA/002/35/2021 | NIA Jaipur     | Ewing Sarcoma | 13th Sept. 2021 in Afternoon.        | A male patient k/c/o Ewing Sarcoma has been coming to the cancer OPD since 2016 - he came to follow - up on 7th sept. 2021 in afternoon for belching, muscular pain, body ache, general weakness, burning & painful micturition, indigestion - he was administered Chitrakadi vati, Chyavanprash, Gokshuradi guggul, syp. Vasaco, Sarpagandha mishran, Avipattikar churna vati - in 2-4 days after consuming the medicines, he suffered from rash with burning sensation on b/l elbow, joint, rt. Flank, upper back side, itching on rt. elbow joint - patient continued all medicines for 14 days. | NA                    | 1. Chitrakadi Vati<br>2. Chyavanprash<br>3. Gokshuradi Guggul<br>4. Syp. Vasaco<br>5. Sarpagandha mishran<br>6. Avipattikar churna vati | NA  | 1. Chyavanprash,<br>2. Chitrakadi vati   | Recovered   | No                     | 29.09.2021        |
| AY-NIA/002/38/2021 | NIA Jaipur     | Piles?        | 16th October 2021 in the evening     | A male patient came to general OPD for intermittent bleeding per rectum, anal prolapse? With Anal tags? - patient had given history of consumption of homemade decoction made by ginger, turmeric, lavang, yashimadhu, giloy for 1 year 2 months ( Approx. from May 2020 ) for preventive purpose from COVID - since June 2021, he is suffering from Intermittent bleeding per rectum, Anal Prolapse Idgree? Anal tags? - he stopped consuming the decoction since July 2021  | NA                    | 1. Tab. Ezee<br>2. Tab. Trifala   | NA  | Homemade Decoction made by Ginger, Turmeric, Clove, Yashimadhu, Guduchi - 50 ml twice a week for one and half year | Recovering Gradually  | No                     | 21.10.2021        |

| ADR Code Number    | Name of (IPvC) | Diagnosis | Date and time of initial observation | Description of A.D.R.  | any chronic disorders | List of all ASU & H Drugs used by the Patient in past one month. | List of other drugs used by the patient during the period of one month: | Name of the Suspected drug for causing ADR | Outcome of the suspected adverse reaction: Recovered/ Not Recovered/ Unknown/ Fatal | ADR: Severe: Yes / No. | Date of Reporting |
|--------------------|----------------|-----------|--------------------------------------|--|-----------------------|--|---|--|---|------------------------|-------------------|
| AY-NIA/002/47/2021 | NIA Jaipur     | Amlapitta | 18th December 2021 in afternoon      | A female patient k/c/o HTN came to general OPD with c/o congestion in throat with prickly pain, dry throat, accumulation of white coloured mucous secretion in throat since 9 to 10 months- patient has given h/o consumption of homemade decoction and pain water vapour inhalation for preventive purpose against COVID-19   | Hypertension          | Decoction of Dalchini, Clove, Jaggery Basal leaves               | Cap. Veloz D, Tab. Atenolol   | Homemade decoction                         | Recovered   | No                     | 04.12.2021        |
| AY-NIA/002/49/2021 | NIA Jaipur     | NA        | 27th January 2022 in the morning.    | A male patient k/c/o Hyperlipidaemia, came for booster dose of Covid 19 Vaccination at CARI. He was administered Samsamami vati under distribution campaign of Ayush prophylactic medicines on 20th January 22 in the morning. Next day he had Giddiness, Headache, Flatulence and fullness in abdomen- after two days he de-challenged the samsamami vati and then reaction abated. | Hyperlipidaemia       | Samsamami Vati, Arogya vardhini, L,iv 52-DS                      | Tab. Itrafaze   | Samsamami Vati                             | Recovered   | No                     | 27.01.22          |



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