



## Add on efficacy of *Gorochanadi Vati* (ayurveda herbomineral formulation) in moderate and severe covid positive subjects with reduced oxygen saturation

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### Abstract

Moderate and Severe cases of Covid-19 have the symptoms such as shortness of breath, difficulty breathing, chest pain, confusion. Standard Covid-19 treatment protocol is regularly adopted. As *Gorochanadi Vati* has the property such as antioxidant, anti-microbial and reduces oxidative stress this study was undertaken as an add on efficacy in moderate and severe Covid-19 positive subjects with reduced oxygen saturation was taken.

**Objective:** To Compare the effect of standard treatment protocol (Control Group) and add on efficacy of *Gorochandi Vati* (Trial Group) in managing moderate to severe Covid 19 associated with reduced O<sub>2</sub> saturation.

**Materials and Method:** Present study was an open labelled clinical study for three days. Total 60 moderate to severe Covid-19 positive subjects fulfilling inclusion criteria was randomly grouped into two groups. Saturation and oxygen required was monitored every hourly for three days and result was analyzed statistically. Repeated measure Anova test, Paired and Unpaired t test, Mc Nemars test were used for data analysis.

**Result:** In Present Study both the groups (Control and Trial group) showed better improvements in SpO<sub>2</sub> with p value (0.015 and 0.048) and Oxygen requirement with p value (0.034 and 0.035) respectively.

**Keywords:** Covid-19, *Gorochandi Vati*, oxygen requirement, SpO<sub>2</sub> saturation

### Introduction

Severe Acute Respiratory Syndrome (SARS) Covid-19 is a series of acute atypical respiratory infections. Globally a total of 210 million cases including 45 lakh deaths have been reported till the end of August 2021<sup>[1]</sup>. Most of the patients with SARS-Covid 19 infection develop a mild illness, approximately 14 % develop moderate to severe diseases that requires hospitalization and oxygen support and 5% require admission in intensive care unit<sup>[2]</sup>. As of now mainly symptomatic supportive treatment is being provided to the patient. It is most contagious during first three days after the onset of symptoms. WHO has set 2 main goals to control the effect of Covid-19 to a minimum<sup>[3]</sup>. First is to prioritize, accelerate innovative research to control the spread of epidemic and facilitate care for those affected. The second objective is learning from current global pandemic response to prepare better for next unforeseen epidemic. Presently majority of the drugs used for treatment worldwide fall primarily under antimalarial, anti-inflammatory, monoclonal antibodies categories and are used solely on an empirical basis<sup>[4]</sup>.

Many researches have been undertaken by Central Council for Research in Ayurvedic Science (CCRAS) to ensure the fast recovery and to provide the quality of life for the

patients from moderate to severe cases of Covid-19. In the present study an *Ayurveda* management in the form of *Gorochanadi Vati* was used as an add on therapy which may be helpful in monitoring oxygen saturation level. As it has anti-microbial, anti-parasitic action and commonly used in cold and cough. Hence this formulation may act on *Pranavaha Srotas* (Respiratory System)<sup>[5]</sup>.

### Materials and Method

For the present study subject who fulfil the criteria of moderate to severe cases of Covid-19 was selected from Sri Dharmasthala Manjunatheswara College of Ayurveda and Hospital Hassan Covid Care Centre and Hassan Institute of Medical Science Hassan.

### Ethical Clearance and Consent

The study was approved by the institutional ethical committee (IEC No: - SDM/IEC/14/2021 and IEC/HIMS/RR 246/10-06-2021) and signed informed consent was obtained from all the patients and study was registered in the CTRI (CTRI/2021/06/034114)

### Sampling Method and Research Design

Total 60 subjects was randomly selected and assigned into two groups of 30 each as Control Group and Trial Group respectively.

**Diagnostic Criteria**

- Real Time Polymerase Chain Reaction Positive Case
- Sign and Symptoms of Moderate and Severe Covid 19 according to ICMR guidelines

**Inclusion criteria**

- Typical clinical presentation of acute onset febrile illness with sore throat and dry cough with or without shortness of breath and a RT\_PCR based laboratory confirmation test for COVID-19
- Patients presenting with or without Typical clinical presentation but having RT\_PCR based laboratory confirmation test for COVID-19
- Patients with either gender, 21 to 70 years age
- Patients with moderate and severe disease with SpO<sub>2</sub> less than 93
- Patients willing to participate and sign an informed consent Understands and agrees to comply with planned study procedures.

**Exclusion criteria**

- Patients suffering from COVID-19 Disease with SpO<sub>2</sub> level below 80 as judged by a physician
- Severe, Unstable, Uncontrolled co-existent medical illness such as Diabetes, Hypertension, Cardiac disorders, liver, kidney disorders and lung disorders or other disease of concern which may put the patient at increased risk during the study
- Active cancer diagnosis, on palliative treatment or requiring current therapy with antimetabolic agents, immunotherapy or radiotherapy.
- Patients on complete parenteral nutrition
- Patients who are likely to worsen or planed ICU admission or ventilator support due to any reason
- Pregnancy and lactation
- Physician decision that involvement in the study is not in the patient's best interest

**Intervention**

- **Control group:** Standard Treatment Protocol (Covid - 19 Kit) + O<sub>2</sub> therapy
- **I. For moderate cases**

**Table 1** <sup>[6]</sup>

SI No	Medicine	Dose	Days
1	Tab Doxycycline 100mg	1-0-1 after food	5 days
2	Tab Vitamin C	1-1-1 after food	7 days
3	Tab Zinc Sulphate	0-1-0 after food	10 days
4	Tab Ivermectin 12 mg	0-0-1 after food	3 days
5	Tab Paracetamol 500mg	1-1-1 after (For fever)	Till fever subsides
6	Tab Cetrizine	0-0-1 (For cold)	Till cold subsides

1. Consider IV methylprednisolone 0.5 to 1 mg/kg or Dexamethasone 0.1to 0.2mg/kg for 3 days (preferably within 48 hours of admission or if oxygen requirement is increasing and if inflammatory markers are increased)
2. Prophylactic dose of UFH or LMWH (e.g., enoxaparin 40 mg per day SC)
3. Monitor for Increased work of breathing (use of accessory muscles), Hemodynamic instability and increase in oxygen requirement

**II. For Severe Cases**

Along with moderate case management (as stated above) Give supplemental oxygen therapy immediately to patients with Severe Covid and respiratory distress, hypoxaemia, or shock: Initiate oxygen therapy at 5 L/min and titrate flow rates to reach target SpO<sub>2</sub> ≥ 90% in adults (Non pregnant)

**Trial group**

Along with standard care of moderate and severe cases of Covid – 19 diseases as mentioned in Control group plus

**Moderate/Severe Covid- 19 Positive subjects**

*Gorochanadi Vati* 125mg - 3 TDS with Luke warm water after food along with standard care

**Sample size:** 30 in each group

**Study design:** Non randomised comparative study

**Assessment Criteria**

1. Clinical Symptoms – Every 8 hrs for three days
2. Oxygen Saturation level – Every hourly for three days
3. Oxygen Input -Every Hourly for three days

**Table 2:** Ingredients of *Gorochanadi Vati* (Ref AFI Vol 1) <sup>[7]</sup>

SI No	Sanskrit Name	Latin Name/Scientific Name
1	<i>Gorochana</i>	Cow bile
2	<i>Rudraksha</i>	Utrasum-bead tress ( <i>Elaeocarpus sphaericus</i> )
3	<i>Chandana</i>	Sandalwood ( <i>Santalum album</i> )
4	<i>Vacha</i>	Sweet flag (rhizome) – <i>Acorus calamus</i>
5	<i>Aklari</i>	<i>Lodochea maldivika</i>
6	<i>Usheera</i>	<i>Vetiveria zizanioides</i>
7	<i>Kamala</i>	Lotus ( <i>Nelumbium speciosum</i> )
8	<i>Naga bhasma</i>	Lead bhasma
9	<i>Kiratatika</i>	<i>Swertia chirata</i>
10	<i>Swarna Bhasma</i>	Gold Bhasma
11	<i>Pravala Bhasma</i>	Corel Bhasma
12	<i>Anjana</i>	Aqueous extract of <i>Berberis aristata</i>

13	<i>Karpoora</i>	Camphor ( <i>Cinnamomum camphora</i> )
14	<i>Jiraka</i>	Cumin seed ( <i>Cuminum cyminum</i> )
15	<i>Dronapushpi</i>	Leucas cephalotes
16	<i>Karpasa</i>	Indian cotton plant ( <i>Gossypium herbaceum</i> )
17	<i>Apamarga</i>	Prickly chaff flower ( <i>Achyranthes aspera</i> )
18	<i>Lashuna</i>	(Garlic ( <i>Alium sativum</i> ))
19	<i>Chirabilwa</i>	<i>Holoptelea integrifolia</i>
20	<i>Shunti</i>	Ginger (rhizome) – <i>Zingiber officinalis</i>
21	<i>Maricha</i>	Black pepper ( <i>Piper nigrum</i> )
22	<i>Pippali</i>	Long pepper ( <i>Piper longum</i> )
23	<i>Agnimantha</i>	<i>Premna corymbosa/mucronata</i> root
24	<i>Ishwari</i>	<i>Aristolochia indica</i>
25	<i>Pata</i>	<i>Cyclea oeltata</i>
26	<i>Shankhapushpi</i>	<i>Clitorea ternatea</i>
27	<i>Neelini</i>	<i>Indigofera tinctoria</i>
28	<i>Haritaki</i>	<i>Terminalia chebula</i>
29	<i>Vibhataki</i>	<i>Terminalia bellirica</i>
30	<i>Amalaki</i>	<i>Emblica officinalis</i>
31	<i>Jatiphala</i>	Nutmeg (fruit) <i>Myristica fragrans</i>
32	<i>Tankana</i>	Borax
33	<i>Mayaphala</i>	<i>Quercus infectoria</i>
34	<i>Shatapushpa</i>	Indian dill (Fruit) <i>Peucedanum graveolans</i>
35	<i>Ajaji</i>	<i>Cuminum cyminum</i>
36	<i>Musta</i>	Nut grass (root) <i>Cyperus rotundus</i>
37	<i>Krishna Jiraka</i>	<i>Nigella sativa</i>
38	<i>Ambara</i>	<i>Spondias pinnata</i>
39	<i>Ardra</i>	Ginger (rhizome) – <i>Zingiber officinalis</i>

**Results**

Present study was conducted to analyze the Add on efficacy of *Gorochanadi Vati* (Ayurveda Herbomineral Formulation) in moderate and severe Covid-19 Positive subjects with reduced oxygen saturation, result is obtained and tabulated as demographic data and clinical features.

**Demographic data**

The subjects tested positive for covid -19 were admitted in the isolation ward of Hassan Institute of Medical Science, Hassan and Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital Covid Care Centre. Out of 60 Subjects, 40 subjects were male and 20 subjects were female.

Out of 60 subjects, 12 subjects were in the age group of 20 to 30, 13 subjects were in the age group of 30 to 40, 8 subjects were in the age group of 40 to 50, 13 subjects were in the age group of 50 to 60, 14 subjects were in the age group of 60 to 70.

**Classification on Basis of symptoms**

Both the groups were assessed on the basis of the symptoms such as Body Temperature, Breathlessness, Weakness, Headache, Loss of Taste present in the Subjects.

**Table 3:** Showing the Result of Body Temperature in Control Group after applying the Paired t test

Body Temperature	N	BT	AT	MD	SD	SE	t Value	P Value
	30	98.82	97.35	1.4677	1.444	0.264	5.563	<0.001

In the present study Control Group, the improvement in Body Temperature Shows statistically significant with P

value <0.001

**Table 4:** Showing the Result of other symptoms in Control Group after applying the McNemar test

Group A		
Symptoms	BT (number of subjects before the treatment)	AT (Number of subjects after the treatment)
Cough	15	10
Breathlessness	15	6
Sore Throat	5	3
Sputum	2	0
Diarrhoea	2	0
Nausea	3	0
Bodyache	15	7
Anorexia	4	3
Headache	16	7
Anosmia	4	1
Loss of Taste	11	4
Weakness	14	5

In this present study control group, Cough was present for 15 subjects before treatment and it was reduced to 10 subjects after treatment. Weakness was present for 14 subjects before and 5 subjects after treatment and others are showed in the Table No 4

**Table 5:** Showing the result of Body Temperature in Trial Group after applying the Paired t test

Body Temperature	N	BT	AT	MD	SD	SE	t Value	P Value
	30	98.6	97.74	0.863	0.752	0.137	6.286	<0.001

In Present Study Trail Group, the improvement in Body Temperature shows statistically significant with p value <0.001

**Table 6:** Showing the result of other symptom in Trial Group after applying Mc Nemar test

Group B		
Symptoms	BT (Number Patient before Treatment)	AT (Number Patient After Treatment)
Cough	15	9
Breathlessness	15	1
Sore Throat	5	2
Sputum	1	0
Bodyache	11	3
Anorexia	2	0
Headache	21	0
Anosmia	7	5
Loss of Taste	9	7
Weakness	9	5

In this present Study Trial Group, Body ache was present for 15 subjects before and 7 subjects after treatment. Weakness was present for 9 subjects before and 5 subjects after treatment and others are showed in the Table No-6

**Table 7:** Showing the result of SpO<sub>2</sub> in Control Group after applying the Repeated Anova measure

BT	AT	Green house geisser	df	mean square	Sig
88.1	96.27	0.015	1.368	13434.12	<0.001

In this present study Control Group, the level of SpO<sub>2</sub> before treatment was 88.1% and after treatment was 96.27% with statistically significant green house geisser value 0.015.

**Table 8:** Showing the result of SpO<sub>2</sub> in Trial Group after applying the Repeated Anova measure

BT	AT	Green House Geisser	Df	Mean Square	Sig
91.33	95.53	0.048	4.229	2249.76	<0.001

In this present Study Trial Group, the level of SpO<sub>2</sub> before treatment was 91.33% and after treatment was 95.53% with statistically significant Green House Geisser value 0.048.

**Table 9:** Showing the result of Oxygen Requirement in Control Group after the applying the Repeated Anova measure

BT	AT	Green House Geisser	df	Mean Square	Sig
4.56	0.73	0.034	2.989	3066.89	<0.001

In this present study, Oxygen requirement before treatment in Control Group was 4.56% and after treatment was 0.73% with statistically significant Green House Geisser Value 0.034

**Table 10:** Showing the result of Oxygen Requirement in Trial Group after applying the Repeated Anova Measure.

BT	AT	Green House Geisser	Df	Mean Square	Sig
2.2	1.2	0.035	3.131	4283.92	<0.001

In this present study, Oxygen requirement before treatment in Trial Group was 2.2% and after treatment was 1.2% with statistically significant Green House Geisser value 0.035

**Table 11:** Showing the result Between the group after applying the Unpaired t test

Symptoms	Group	N	Mean	S.D	S.E	T	P value	Remarks
Temperature	Group A	30	98.82	1.214	0.222	0.755	0.259	Non-Significant
	Group B	30	98.60	0.999	0.182	0.755		
Cough	Group A	30	0.83	0.379	0.069	0.328	0.513	Non-Significant
	Group B	30	0.80	0.407	0.074	0.328		
Breathlessness	Group A	30	0.70	0.466	0.085	1.325	0.028	Significant
	Group B	30	0.53	0.507	0.093	1.325		
Sore throat	Group A	30	0.27	0.450	0.082	0.293	0.559	Non-Significant
	Group B	30	0.23	0.430	0.079	0.293		
Sputum	Group A	30	0.07	0.254	0.046	0.584	0.242	Non-Significant
	Group B	30	0.03	0.183	0.033	0.584		
Diarrhea	Group A	30	0.07	0.254	0.046	1.439	0.003	Significant
	Group B	30	0.00	0.00	0.00	1.439		
Nausea	Group A	30	0.10	0.305	0.056	1.795	0.001	Significant
	Group B	30	0.00	0.00	0.00	1.795		
Body ache	Group A	30	0.73	0.450	0.082	2.154	0.008	Significant
	Group B	30	0.47	0.507	0.093	2.154		
Anorexia	Group A	30	0.23	0.430	0.079	1.828	0.001	Significant
	Group B	30	0.07	0.254	0.046	1.828		
Headache	Group A	30	0.77	0.430	0.079	0.576	0.254	Non-Significant
	Group B	30	0.70	0.466	0.085	0.576		
Anosmia	Group A	30	0.17	0.379	0.069	0.637	0.204	Non-Significant
	Group B	30	0.23	0.430	0.079	0.637		
Loss of taste	Group A	30	0.50	0.509	0.093	0.254	0.720	Non-Significant
	Group B	30	0.53	0.507	0.093	0.254		
Weakness	Group A	30	0.63	0.490	0.089	1.158	0.159	Non-Significant
	Group B	30	0.48	0.509	0.094	1.158		

**Discussion**

In the present study, Moderate to severe covid-19 cases showed good improvement in Control and Trial groups. In this study Control Group was given standard treatment protocol of medicines with regular oxygen monitoring which showed good improvement, whereas Trial group was

given *Gorochanadi Vati* which showed significant decrease in total duration of symptomatic phase, oxygen saturation and O<sub>2</sub> requirement (saturation level) and also marked improvement was seen in breathlessness, headache, and Body ache. *Ayurveda* intervention in this study i.e *Gorochanadi Vati* consists of 39 drugs, drugs like *Usheera*,

*Kamala, Kiratatiktha, Trikatu, Pravala* which is very useful in patient having fever. Diarrhea and loss of taste, may be due to the *Pittahara (pacifies Pitta), Tiktha Rasa* (bitter taste) having *Jwara hara* action (fever), *Sheeta Virya* (cold potency) *Dravya* possessing *Sthambana Guna* (to stop or block) helps to control diarrhea<sup>[8]</sup>.

Drugs such as *Triphala, Svarna bhasma, Lashuna, Chirabilwa, Tankana, Ardraka, Krishna Jeeraka* is very helpful in treating symptoms like sputum, body ache, malaise, anosmia may be due to *Kaphara* property of *Lashuna, Chirabilwa, Tankana bhasma* has antimicrobial and antibacterial action helpful in decreasing the viral load, *Ushna* (hot potency), *Rochaka guna* (digestive and carminative) of *Ardraka* helps to tackle anosmia, headache. *Trikatu* increases the metabolic process by quick absorption of nutrients<sup>[9]</sup>. *Gorochana* is predominant of *Tiktha Rasa* having *Vrushya* (aphrodisiac), *Pachani (digestive)* and also *Krimighna hara*, best *Amahara* properties and helps in increasing the saturation level by decreasing the viral load<sup>[10]</sup>. *Vacha* reduces and aid in swelling reduction following an injury. *Kamala* agents that reduces oxidative stress and revert oxidative damage in the body cells, hence it may be worked in managing the oxidation stress. *Maricha* helps to reduce the secretion of phlegm in the respiratory tract and henceforth clearing the airway for respiration<sup>[11]</sup>. *Kalanji* helps to manage the symptoms of cough and difficulty in breathing. It may be stated that response to the infection was better addressed by combined effect of systemic and local action by drug intervention of Control Group and Trial Group.

### Limitation of The Study

Since this was study conducted on 60 subjects of moderate to severe cases of Covid -19, intervention of *Gorochanadi Vati* in Trial Group was only for 3days, increase in the duration may provide better option to know the action of the drug

### Conclusion

Control Group had showed significant in saturation and Oxygen and whereas Trial Group had showed significant results in both saturation and oxygen requirement and showed significant within the groups. However Trial Group showed significant result managing Breathlessness, headache and Body ache. Due to encouraging outcomes of this trial, these drugs can be used in clinical practice too, this paves way to an integrated approach.

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