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Role of Raj Nirvan Bati in Treatment of COVID19 RT-PCR Positive Cases

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ABSTRACT

Background: The count of Corona virus disease of 2019 (COVID19) infection and deaths is raising each day and as per the data from all around the globe shows the 7145539 persons are infected and 408025 the COVID19 deaths have occurred till on 10 June 2020. **Aim:** The present study was conducted to explore the role of Raj Nirvan Bati for the treatment of COVID19 cases. **Methodology:** Total of 30 reverse transcription polymerase chain reaction (RT-PCR) COVID19 confirmed cases were taken in the present study. Raj Nirvan Bati (RNB), was given 125 milligrams per dosage 2 times a day with 5 ml of honey. **Results:** Cough, fever, and pain in throat were the most common symptoms present in 22 (73.3%), 17 (56.7%) and 12 (40.0%) cases on the day of admission, respectively. Twenty-five (83.3 percent) cases became negative on RT-PCR COVID19 testing after 5 days of treatment with the Raj Nirvan Bati. **Conclusion:** Most positive cases of RT-PCR SARSCoV2 transformed to negative test status and improvement occurred in most hematological cases after five days of Raj Nirvan Bati treatment. lactate dehydrogenase (LDH), aspartate aminotransferase (AST), alanine transaminase (ALT) and C-Reactive Protein may be used as surrogate marker for the COVID19 disease, as they were found raised in many cases in the present study. There were no adverse effects of RNB therapy and no clinical profile deterioration was noted during the duration of the study in any case. Therefore, randomized controlled trials should be conducted to check the safety and efficacy of the Raj Nirvan Bati.

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INTRODUCTION

The count of Corona virus disease of 2019 (COVID19) infection and deaths is raising each day and as per the data from all around the globe shows the 7145539 persons are infected and 408025 the COVID19 deaths have occurred till on 10 June 2020.**[1]** There is no successful cure or vaccine searched to date and, given considerable work on this pandemic, the death rate is rising day by day. Thus, the indigenous drugs need to be looked at as few Ayurvedic treatments have been proven to increase the human body's innate immunity and to combat many viral and bacterial diseases. The present work was conducted with the assistance of modern technology to explore the novel Ayurvedic preparation (Raj Nirvan Bati) for outcomes in SARSCoV2 cases.

METHODOLOGY

Study place: The current research was conducted at the University of Medical Sciences of Uttar Pradesh, Saifai, Etawah, India. **Sample size and inclusion and exclusion criteria:** A total of 30 symptomatic cases with admitted age of ≥18 years with positive reverse transcription polymerase chain reaction (RT-PCR) test for SARS CoV2 were included even if they had co morbid condition. Patients with estimated glomerular filtration rate (eGFR)< 60 ml/minute, lactating and pregnant females, critically ill patients (oxygen saturation i.e. Spo2 < 90%, in shock or altered sensorium), who did not give consent, were not included in the study. In mild symptomatic group, those cases were included who had symptoms of fever, cough with SpO_2> 94% saturation without dyspnea. Symptomatic cases having fever and cough with dyspnea and SpO_2 > 94% were taken in to moderate symptomatic group. Symptomatic cases that had fever and cough with dyspnea and SpO_2 between 90-94% requiring Intensive Care Unit admissions were included in severe symptomatic group.

Drug formulation: Finely processed and almost like nano-particle of gold and silver, highly purified and refined mercury, clamina perpeta, arsenic trioxide (hartala bhasma), black pepper (Piper Nigrum), nag daman (Artemisia Nilagirica), celery (Carum Copticum), kharpar (A zinc containing compound) and niramish are the major constituents of Raj Nirvan Bati (RNB). As per Ayurvedic principles, all compounds in this preparation are at the prescribed permissible level. **Procedure:** Each study subject received 125 milligrams of RNB powder twice daily with 5 ml of honey per dose. Specific scientific care procedures and specific therapies were prescribed to each patient according to current knowledge.

Hydroxychloroquine was administered as per guidelines. Vitamin B-complex with Zinc was also provided as normal co-morbidity care offered to each patient by the specialists concerned.

Ethical consideration: The informed consent of each participant was obtained at the time of their enrolment in the study. The University's Ethics Committee / Corona Committee had given ethical clearance.

RESULTS:

The research has included a total of 30 cases. The mean age of study subjects was 44.2± 16.94 years with a range of 22 to 80 years and 23 cases were male (76.7 percent). Among 6 cases (20.0 percent) admitted with co-morbid conditions, diabetes was found. [Table1]

Table No. 1: Demographic parameters and comorbidity profile of study subjects

Parameter	**Number**	**Percentage**
Age-Group in years		
18 to 39	13	43.3
40 to 59	11	36.7
60 to 80	06	20.0
Gender		
Male	23	76.7
Female	07	23.3
Cases with Comorbidities*		
Diabetes	06	20.0
Hypertension	03	10.0
Coronary artery disease/ Ischemic heart disease	02	6.7
Chronic Liver Disease	01	3.3
Bronchial Asthma	01	3.3

***Multiple findings in a case

In 23 cases (76.7 percent) there were mild symptoms. Whereas in 5 (16.7 percent) and 2 (6.6 percent) cases there were moderate and severe symptoms, respectively. [Table 2]

Table No. 2: Severity status of SARSCoV2 positive cases

Severity status	Number	Percentage (%)
Mild	23	76.6
Moderate	5	16.7
Severe	2	6.7

Cough, fever, and pain in throat were the most common symptoms present in 22 (73.3%), 17 (56.7%) and 12 (40.0%) cases on the day of admission, respectively. The most common symptom after 5 days of starting treatment with Raj Nirvan Bati was fatigue in 5 cases (16.7) followed by cough and fever in 4 cases (13.3 percent) and 2 (6.7 percent) respectively. [Table 3]

Table No. 3: Clinical profile of study participants on the day of admission*

Symptoms	Day-1 Number (%)	Day-5 Number (%)	Day-10 Number (%)
Fever	17 (56.7)	2 (6.7)	0 (0.0)
Cough	22 (73.3)	4 (13.3)	0 (0.0)
Throat pain	12 (40.0)	0 (0.0)	0 (0.0)
Dysponea	7 (23.3)	0 (0.0)	0 (0.0)
Headache	9 (30.0)	0 (0.0)	0 (0.0)
Fatigue	11 (36.7)	5 (16.7)	1 (3.3)
Alteration in sensation of taste	2 (6.7)	0 (0.0)	0 (0.0)

***Multiple findings in a case

There were 9 (30.0 percent) cases in the present study that indicated lymphocytopenia neutrophilia at the time of admission. Among 7 (23.3 percent) cases, hemoglobin concentration was less than 11 gm/dl. C-reactive protein (CRP) was found to be positive in 17 cases (56.7%) and creatinine phosphokinase increased in 9 cases (30.0%). Lactate dehydrogenase (LDH) was increased in 25 cases (83.3%). In 17 cases (56.7%) serum glutamate pyruvate transaminase was increased, and in 10 cases (33.3%) serum glutamic-oxaloacetic transaminase was increased. The finding of Chest X-Ray posteroanterior (PA) view showed that lung involvement in 9 (30.0 percent) cases. Ground glass opacity, consolidation, and pleural effusion were present in 6 (20.0%), 8 (26.7%) and 2 (6.7%) cases respectively.[Table 4]

Table No. 4: **Lab and Chest X-ray (PA View) findings of the cases**

Parameter	Range	Number	Percentage
Total Leucocyte Count (mm^3)	4000-11000	25	83.3
	>11000 mm^3	5	16.7
Differential Leucocyte Count (DLC)	Neutrophilia with lymphocytopenia*	9	30.0
	No Neutrophilia with lymphocytopenia	20	66.7
	Lymphocytosis	1	3.3
Hemoglobin (gm/dl)	11-16	23	76.7
	<11	7	23.3
Platelet count (lacs/mm^3)	<1.5	15	50.0
	1.5-4	15	50.0
C-Reactive protein (CRP)	Positive	17	56.7
	Negative	13	43.3
SGOT (IU/mL)	0-45	20	66.7
	>45	10	33.3
SGPT (IU/mL)	0-45	13	43.3
	>45	17	56.7
CPK (IU/mL)	<130	25	83.3
	>130	5	16.7
LDH (IU/mL)	<230	5	16.7
	230-460	17	56.7
	>460	8	26.6
S. Creatinine (mEq/Litre)	0.1-1.2	21	70.0
	>1.2 but <1.5	9	30.0
Chest X-ray (PA View) findings**	Ground glass opacity	6	20.0
	Consolidation	8	26.7
	Pleural effusion	2	6.7
	U/L lung involvement	6	20.0
	B/L lung involvement	3	10.0

*Neutrophilia >75% of differential leucocyte count (DLC); Lymphocytopenia <20% of DLC;
**Multiple findings in a case

Twenty-five (83.3 percent) cases became negative on RT-PCR COVID19 testing after 5 days of treatment with the Raj Nirvan Bati. On the 12th day of treatment with RNB, remaining 2 cases became negative. In any case, there was no adverse drug effect on vitals after taking the medication. [Table 5]

Table No. 5: **Outcome of Raj Nirvan Bati (RNB) on the study subjects**

COVID-19 RT-PCR of throat and nasopharyngeal swab	Day of start of RNB Therapy	Test Result	
		Positive	Negative
	1st Day	30 (100.0)	00 (0.0)
	5th day	05 (16.7)	25(83.3)
	10th day	02 (6.7)	28 (93.3)
	12th day	00 (0.0)	30 (100.0)

DISCUSSION

Some of the Ayurvedic treatments have been proven to increase innate immunity and this was the rationale behind choosing each ingredients of Raj Nirvan.

Immune modulation and anti-inflammatory effect: In a study by Kuttan G., it was observed that the total number of white blood cells increased following dosages of some sulphur compounds.**[2]** The development of cytokine induced by edema and Ultra Voilet-B decreased after treatment with silver nanoparticles. Mercury compounds showed analgesic, anti-inflammatory, and lymphoproliferative response to T cell mitogen.**[3,4,5]** There's evidence that C.coptium can stimulate beta 2 receptors. Also found was C. Copticum blocks histamine (H1 receptors) and thus has a relaxing effect on the bronchial smooth muscles.**[6,7,8]** Pimetine (found in black pepper) acts as a mucolytic agent, thus reducing the replication of viruses in the upper respiratory tract mucosa. **[9,10]** That was why sulfur, probable nano gold and silver particles, C.copticum and pimentine were included for RNB preparation.

Anti-viral action: A analysis of the **Yamamoto K. *et al*** has shown that four nucleosides containing Sulphur may inhibit the spread of influenza virus.**[11]** A research done in 2010 revealed that zinc cations (Zn++) can inhibit SARS coronavirus RNA polymerase. **[12]** A study done in 2014 showed a slow-down effect of silver nanoparticles on influenza virus replication indicating its virucidal effect.**[13]** It also appears that the RNB preparation had some antiviral effect, as is apparent from the results of symptom reversal and also the RT-PCR test results. **Upper and lower respiratory tract system effects:** A study on a compound of sulfur (Methylsulfonylmethane) for allergic rhinitis showed a significant reduction in symptoms of the respiratory tract.**[14]** A study showed that there was a decrease of acute lower respiratory tract infections, and the stay in the hospital was shorter among

children receiving zinc supplementation.**[15]** Thus, purified sulfur and zinc compound were included as a component of Raj Nirvan Bati.

Effect of ingredients on microbes: A study done on Arsetnic trioxide showed inhibition of streptococcus pneumonia & Staphylococcus aureus.**[16]** Indian wormwood (Artemisia nilagirica) showed inhibitory action on bacteria (both gram positive and gram negative).**[17]**

A study done in Wuhan, China showed that leukopenia, lymphopenia, raised aspartate aminotransferase was present among 25%, 25% and 37% patients respectively. These findings are similar with the findings of the present study.**[18] Huang C *et al*, Zhang J *et al*** and **Chen L *et al*** in their researches in China showed that 75.0%, 63.0%, and 69.0% of COVID19 positive cases had a reduction in lymphocytes respectively, similarly as the present research. In the present study, hemoglobin levels of 23.7 percent COVID19 positive cases have been reduced. Similar findings have been found in a study in Wuhan (China), where 41.0 percent of cases showed reduced levels of Hemoglobin.**[18,19,20]** The present study showed elevated levels of Lactate Dehydrogenase (LDH) among 25 (83.3%) COVID19 positive cases. Nearly similar results were found in 5 studies conducted in China where LDH levels rose between 73.0 percent, 76.0 percent, 27.0 percent, 92.0 percent and 69.0 percent respectively.**[18,20,21,22,23]** The serum ALT levels were raised in 28%, 17% and 17% respectively in 3 studies done in China, whereas it was found within normal limits among 2 studies.**[18,19,20,21,23]** Nearly comparable findings were seen in the present study where 17 cases (56.7 percent) showed an elevated ALT level. Some studies in China showed the increased levels of AST between 37%, 35%, 16% and 8% respectively, which is consistent with the results of this study, which showed an increase in AST in 10 cases (33.3%).**[18,21,22,23]** A systemic review of 919 patients conducted by Salehi S et al showed bilateral involvement of the lung in 87.5 percent of cases of SARS CoV2 while consolidation was found in 31.8 percent of cases. The present study found that only 3 (10.0%) patients had involvement in the bilateral lung whereas consolidation was present among 8 (26.7%) cases.**[24]**

CONCLUSION

Most positive cases of RT-PCR SARSCoV2 transformed to negative test status and an improvement occurred in most hematological cases after five days of Raj Nirvan Bati treatment. Thus, it can be hoped that Raj Nirvan Bati will be used to treat positive cases of

SARSCoV2 to reduce the burden of this latest pandemic on the health sector. LDH, AST, ALT and C- Reactive Protein may be used as surrogate marker for the COVID19 disease, as they were found raised in many cases in the present study. There were no adverse effects of RNB therapy and no clinical profile deterioration was noted during the duration of the study in any case. Therefore, randomized controlled trials should be conducted to check the safety and efficacy of the Raj Nirvan Bati.

LIMITATIONS

Given that the study's sample size was small, the results could not be generalized to populations. So, research on larger sample size is needed.

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