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Raj Nirwan Bati: Scientific Ingredients and Effect on COVID-19 Patient's Recovery



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ABSTRACT

Background and purpose: Today, the major serious health challenge globally is COVID-19 pandemic. Many health care systems are trying to find a solution to this pandemic. Based on the ancient principles of Charaka Samhita, Raj Nirwan Bati, an ayurvedic proprietary medicine was formulated from various herbs and minerals after purification and screen before referrals of modern medicine. This study aimed to analyze the effect of Raj Nirwan Bati (RNB) on the recovery of COVID-19 patients, to assess the effect of RNB on both sexes for their recoveries, to identify the effectiveness of RNB on COVID-19 patients with comorbidities and without comorbidities COVID-19. **Methods:** Thirty confirmed COVID-19 cases after their lab diagnoses were selected for this study. Symptomatic cases were given RNB along with other prescribed medications and the recovery time was calculated. **Results:** All the parameters were expressed in Mean \pm SD, and unpaired 't' test was used to calculate the statistical significance. There was a fast recovery in COVID-19 patients with a mean value of 5 days. Results shown that there was no difference in the recovery time in respect to sex and comorbidities. **Conclusion:** Raj Nirwan Bati (RNB) prepared from various herbs and minerals after purification shall have the beneficial therapeutic effects in COVID-19. It reduces the clinical features caused by COVID-19 and can boost up the immunity. It also helps in fast recovery of the patients in both sexes, comorbidities as well as non-comorbidities cases.

INTRODUCTION

Since December 2019, the whole world is experiencing a devastating situation, COVID-19, a pandemic declared by World health organization (WHO) having origins from China¹. The disease has spread to around 186 countries, 6,568,739 cases were positive and 3, 87,957 deaths occurred globally as on 03-06-2020². Despite the global efforts, the pandemic is continuing to spread, and a need of clinically proven prophylaxis and therapeutic protocol is in high demand³. Extracting the secrets, from ancient ayurveda classics, Charaka Samhitha, could find a solution for the efforts in combating COVID-19. The disease in China is now under control⁴ which may be because of Traditional Chinese Medicine (TCM)⁵ having some similar principles with Ayurveda. Indian Buddhist monk and Ayurvedic teacher and practitioner Bodhidharma had spread the concept of Ayurveda to China in 5th century⁵.

The main clinical features of COVID-19 are fever, cough, sore throat, headache, fatigue, myalgia and dyspnoea⁶ due to hyperactivated CD4 and CD8 cells with high concentration of proinflammatory cells. There will be microsteatosis leading to liver damage.

The aims of this study are to analyze the

- a. Effect of Raj Nirwan Bati (RNB) on recovery of COVID-19 patients.
- b. To assess the effect by comparing males and females on recovery.
- c. To identify the effectiveness of RNB on COVID-19 patients with comorbidities and compare without comorbidities.

METHODOLOGY:

A sample of 30 confirmed COVID-19 patients, both males (N=23) and females (N=7) were recruited for the study after taking written consent. The study is approved by the Institutional Ethical Committee and Clinical Trials Registry-India (CTRI). The patient's age and sex was noted. The number of days taken for RT PCR to become negative was recorded to identify the number of days taken for recovery. The patients are discharged after confirmed lab report of COVID-19 negative status as per the state protocol. After admission, the patients were screened for Hemoglobin, Total Leukocyte count (TLC), Platelet count, SGOT, SGPT, CPK, LDH, Serum creatinine. The mean +/- SD values are described in Table 1. The patients were also screened for any comorbidities and recorded. The COVID-19 cases with comorbidities

are 9 and non-comorbidities are 21. All the cases were symptomatic. The patients were given RNB (**Fig 1**) 125 mg mixed with 5 ml of honey twice daily empty stomach before meals, along with the prescribed medical management for COVID-19 as well as for comorbidities if any under the supervision of senior physicians.

The various ingredients used in the RNB are Sulphur, Coral, Gold, Silver, Orpiment, Mercury, Pearl, Zinc, Black pepper, Nagdamini, and Nirvisha. These elements possess the properties of antibiotic, anti-infectious, cytotoxic, detoxification, antioxidant, immune boosting. The various therapeutic uses, their physiology of action and possible adverse effects are described below.

SULPHUR: It is also known as Gandhaka, a yellow crystalline element found in beds of gypsum is a non-metallic solid element. (**Fig 2a**) Purified Sulphur is used in cough, asthma, general debility, chronic fevers, depression, fibromyalgia, arthritis, intestinal cystitis, athletic injuries, congestive cardiac failure, diabetes, cancer and AIDS⁷.

Physiology of Action: The plasma thiols present in the SAA (Sulphur Amino acids) have pro-oxidant and anti-oxidant properties⁸. N- acetylcysteine (NAC), glutathione, and alpha lipoic acid have been shown to interrupt the process of viral activation and CD4 cell death⁹.

Adverse effects: headaches, dizziness, nausea, and diarrhea.

CORAL: Coral is known as Praval or Moongain in ayurveda which is used in ayurvedic therapeutics since ages. (**Fig. 2b**) It is used as anti-inflammatory, antitussive, antipyretic, antimicrobial, anti-bone loss, cytotoxic, antihypertensive agents¹⁰. It is also used in non-productive cough, general debility, headaches¹⁰.

Physiology of Action: Diterpenes are one specific class of molecules isolated from corals that have been shown to exhibit therapeutic benefits, specifically anti-inflammatory and antimicrobial activities¹⁰. Novel steroids isolated from *Sinularia crassa* were found to down regulate expression of pro inflammatory proteins and showed cytotoxic activity against human liver cancer cells^{9,10}.

Adverse effects: Oral use of Coral is except in some cases where lead poisoning on long term use can occur. Pregnant and lactating women should use with precautions.

GOLD: Gold also known as Swarna in ayurveda is an important, noble metal used to influence immunological responses. (Fig. 2c) Since historic times it is used in the treatment of diseases such as smallpox, ulcers skin and measles¹¹ and cancer.

Physiology of Action: Gold has a high degree of resistance to bacterial colonization^{12,13}. The gold suppresses the anaphylactic release of histamines.

Adverse effects: pruritis, dermatitis, stomatitis and proteinuria.

SILVER: Colloidal silver also known as Rajata is effective in killing and preventing bacterial growth, including bacteria and antibiotic resistant bacteria¹⁴ and viruses in general. It is also effective in preventing viruses from entering human cells and toxic to cancer cells. (Fig 2d)

Physiology of Action: silver particles have the ability to kill microbes because airway block or break the outer walls of the bacteria. Silver ions can lead to denaturing of protein and cell death because of their reaction with nucleophilic amino acid residues in proteins and attach to sulfhydryl, amino, imidazole, phosphate and carboxyl groups of membrane or enzyme proteins, silver also known to block the cells respiration, inhibit a number of oxidative enzymes and produce the cell membrane rupturing for the attachment of silver ions or nanoparticles to the bacteria base on electrostatic interactions^{15,16}.

Adverse effects: Argyria, permanent bluish discoloration of skin, renal and hepatic dysfunction, hemolytic anemia.

ORPIMENT: Used as louse-killer, a cure for scabies, for snake bites, insect stings, and skin diseases, Detoxification and laxative use, effective in killing leukemia K562 cells in vitro antispasmodics, psoriasis¹⁸. (Fig 2e)

Physiology of Action: It provides suitable therapeutic effects for the patients of skin cancer or skin metastasis by inhibiting A431 proliferation^{19,20}.

Adverse effects: skin lesions, vascular toxicity, respiratory, renal and liver toxicity.

MERCURY: Also known as parade in ancient medicine, used to prolong life, heal fractures, and maintain generally good health, has sedative and hypnotic effects²¹. (Fig 2f)

Physiology of action: The macro particle size of the drug matches well with the colloidal size and this suggest the possibility that these colloidal particles get attached to the human intestine and provide a large surface area thereby increasing the absorption of other nutrients and drugs, it helps in Creation of healthy cells and tissues in human body^{22,23}.

Adverse effects: Renal failure, death, lung and brain dysfunction.

PEARL: it is used in treating various skin and bone related disorders due to its abundant proteins and mineral contents. **(Fig 2g)** It has antioxidant properties.

Physiology of Action: The antioxidant properties are due to the prominent protein bands near the molecular weight 17 kDa and 72 kDa. The hydrophobic amino acids in Pearl extract like Val, Ile, Leu, Met, Phe, Trp, and Cys were reported to show higher free radical scavenging ability. Pearl powder was used as an anti-inflammatory, detoxifying agent, and relaxant in Chinese medicine. This could be in part because of the magnesium. Magnesium has an ability to elevate gamma aminobutyric acid (GABA) levels, which can help alleviate depression, anxiety, and certain sleep disorders²⁴.

Adverse effects: Redness, itching, or swelling due to allergy to calcium present in the pearl.

ZINC: Zinc, a trace element has an important role in human physiology. **(Fig 2h)** Zinc after purification has been used as antioxidant, immune booster helps in reproduction, essential for good eye vision. It also helps in wound healing and was used from ancient times by Ayurvedic physicians. Puspanjana (ZnO) is used as antitussive and antipyretic agent²⁵.

Physiology of action: Zinc is involved in the function of cells contributing to non-specific immunity such as neutrophils and natural killer cells and plays an important role in T-lymphocyte function for development of acquired immunity. Zinc has regulatory role in cell signaling and influence nerve impulse conduction also plays a role in apoptosis²⁵.

Adverse effects: Excessive zinc results in zinc toxicity resulting in ARDS, dyspnoea, airway inflammation GI bleeding, lethargy, anemia, dizziness and copper deficiencies.

BLACK PEPPER (Kali Mirch): It is used mostly for menstrual and ear-nose-throat disorders. The black pepper has antioxidant, antitumor, anticonvulsant, analgesic, anti-inflammatory, antidiarrheal, immunomodulatory, antibacterial, antiviral, antifungal and hepatoprotective effects^{26, 27, 28}. **(Fig 2i)**

Physiology of action: The antimicrobial activity of the black pepper is due to the chemical constituents present in it. It inhibits the further growth of bacteria, viruses and fungus.²⁹ The alkaloids and carbohydrates present in the black pepper results in anti-diarrheal activity.^{27,29} The black pepper reduces synthesis of PGE2 and also via opioid pathways shows analgesic and antipyretic effects³⁰.

Adverse effects: Burning sensations in stomach and throat.

NAGDAMINI (*Piperia lappacea*) used for treating inflammatory disorders, fracture healing, cough, fever, anticancer agent. The roots of Nagdamini have an antitussive effect³¹. It also has antioxidant effects. **(Fig 2j)**

Physiology of action: It blocks the effect of cyclooxygenase (COX) a key enzyme in prostaglandin synthesis which shows anti-inflammatory and analgesic effects³². The alkaloids present in Nagdamini act as cough suppressant³¹.

Adverse effects: Vomiting in high doses, infertility, precautions should be taken in pregnant and lactating women.

NIRVISHA (*Delphinium denudatum*). It is used to reduce pain and treating cough and wounds. The roots are used in treating the cough. It also has antipyretic effects³³. **(Fig 2k)**

Physiology of Action: The analgesic activities of C18- and C19-diterpenoid alkaloids have been extensively investigated since 1981, among which 3-acetylcarnitine, lappaconitine and crassicauline A, have been reported to exhibit remarkable analgesic activities and have been developed to be analgesic drugs clinically used for the treatment of various pains in China³³.

Adverse effects: Acute toxic reactions.

All the minerals were added in proper doses to avoid adverse effects.

All cases were also given Raj Nirwan Quath (RNQ), a decoction made from Large and small cardamoms (Elaichi), Ajowan (Ajwain), Cinamon (Dalchini), Curcumin (Haldi), Ginger (Adhrak), Black Pepper (Kali Mirch), dry gourd (Sonth), and Tulsi. The Kadha was delivered 100 ml two times a day. The effects of RNQ was analyzed and manuscript was submitted to another scientific journal.

RESULTS

The age, investigations are expressed in Mean \pm SD. The mean age of Males (N=23) is 44.39 \pm 16.30, females (N=7) is 45.85 \pm 21.95. The mean values of investigations were taken, the SGOT, SGPT, CPK, Serum creatinine, LDH levels were found higher than the normal values. (Table 1). The Net days taken for recovery were compared among males and females to find out if the sex has any role on the time taken for recovery, and also among patients with comorbidities and non-comorbidities to check the effectiveness of RNB. An unpaired 't' test was used to find the level of statistical significance at 5 % ($p\leq 0.05$). The mean days of recovery for males (N=23) is 5 \pm 2.11, for females (N=7) is 5, t value is 0, p value is 1, the result is not significant at $p<0.05$, indicating there is no statistical significant difference on recovery time in males and females. The mean of days of recovery with patients with comorbidities (N=9) is 4.55 \pm 0.72 and non-comorbidities (N=21) is 5.1 \pm 2.1 t-value IS 0.863 and p value 0.395, the results are not significant at $p<0.05$ indicating the effect of RNB has no difference on comorbidities and non-comorbidities COVID-19 patients.

DISCUSSION

In this study, to analyze the effects of Raj Nirwan Bati (RNB), on COVID-19 cases in terms of sex, Comorbidities status, the results shown that the RNB has similar effects on recovery time in both the sexes, comorbidities and without comorbidities cases.

Ayurveda, since 7th century BC, has been an important system of medicine with proven scientific results in combating pandemics like smallpox. Various herbo-mineral preparations have been used to control infections and boost immunity. Siddha Nagarjuna was considered as father of Ayurvedic mineral preparations and is commonly called as Rasa Sastra.

The mineral preparations are called as bhasmas. A variety of purification techniques are employed for safe usage of these minerals for therapeutic purposes.

The most common symptoms in COVID-19 are high fever, flu, non-productive severe cough, body pains. The RNB is prepared from the bhasmas of various minerals has all the abilities to combat these symptoms. The ingredients in the RNB like Sulphur, Coral and Zinc suppresses the cough and act as antitussives. Nagadhamini and Nirvisha act as cough suppressants and bronchodilators^{31,32}. These minerals also help in reducing the raised body temperature and act as antipyretic agents. The gold, silver, and black peppers are best known for their

antimicrobial activities. The nanoparticles of gold and silver are now widely used in combating various infections. The pearl, mercury, orpiment minerals act as antioxidants and also aids in boosting the immunity. It is evident that in COVID-19, there will be damage to liver, due to increased mononuclear infiltrates, Black pepper reduces them and is best known for its hepatoprotective effects. The novel coronavirus also cause diarrhea in some patients. The sulphur and black pepper act as anti-diarrheal agents. In covid-19 cases there will be symptoms of pneumonia which includes pain, the various ingredients of RNB like black pepper, sulphur, coral, nagdamini, nirvisha has anti-inflammatory and analgesic effects. Silver has antiviral properties. It reduces the activity of HIV, hepatitis C and other general viruses by interfering the enzymes that allow the virus to utilize oxygen and preventing its damage to the body.

CONCLUSION:

COVID -19 is a serious pandemic that the whole world is fighting. Many systems of healing are considering various therapeutic principles to combat this infection. Ayurveda has a proven track record of fighting against pandemics since historic times. Raj Nirwan Bati (RNB) prepared from various herbs minerals after purification showed the beneficial therapeutic effects in COVID-19. It reduces the cough, fever, body pains and boosts up the immunity. It also helps in fast recovery without adverse effects of the patients in both sexes, Comorbidities and without comorbidities cases.

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Table No. 1: Mean \pm SD of various investigations at the time of admission.

Investigation*	Mean \pm SD	Normal values	Report
Hemoglobin (gms%)	12.04 \pm 2.11	12-16	Under normal level
TLC (/dl)	7717.66 \pm 2817	4000-10,000	Under normal level
Platelets (/dl)	1.59 Lakhs \pm 0.80	1.50 to 4.00	Under normal level
SGOT (u/l)	45.73 \pm 33.51	5-40	Increased
SGPT (u/l)	69.23 \pm 55.63	7-56	Increased
CPK (u/l)	134.56 \pm 205.55	39-308	Increased
LDH (u/l)	405.56 \pm 219.04	140-280	Increased
S. creatinine (mg/dl)	1.054 \pm 0.286	0.84-1.21	Increased
*N=30			



Figure No. 1: Raj Nirwan Bati (RNB)



Figure No. 2a-k: Various ingredients of Raj Nirwan Bati (RNB)