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CLINICAL STUDY TO EVALUATE THE YOGVAHI EFFECT OF RASASINDOOR WITH AQUEOUS EXTRACT OF ECLIPTA ALBA IN MANAGEMENT OF ESSENTIAL HYPERTENSION

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ABSTRACT

Background

Hypertension is a growing problem in India and causes a significant burden on the health system. Well-managed and well-controlled hypertension leads to a better quality of life and reduces the risk of complications, which include coronary artery disease, heart failure, cerebrovascular disease, and chronic kidney disease. The disease hypertension does not have a direct correlation with any *Vyadhi* in *ayurvedic*classics, so *Vyadhi Pratyanika Chikitsa*is not found directly, and we focus on *Dosha Pratyanika Chikitsa* for the management of this disease. On the basis of a previously done experimental study, an aqueous extract of *Eclipta alba (Bhringraj)* is selected as an antihypertensive drug. In the literature, apart from *VataNiyamak, hridya, sothahara* and the neurine tonic action of *Rasasindoor, Yogavahi*(bioenhancer) action is also mentioned.**Objective**: To evaluate the *Yogvahi* effect of *Rasasindoor* with an aqueous extract of *Eclipta alba* in the management of Essential Hypertension. **Methods**: 100 patients with Essential Hypertension having Blood pressure upto stage 1 according to the 7th JNC criteria for Diagnosis of Hypertension systolic blood pressure with a maximum limit of 160 mm of mercury and diastolic blood pressure maximum limit of 100 mm of mercury will be randomly allocated to two groups having 50 patients in each group.**Group A** will be given an aqueous extract of *Eclipta alba* 500 mg twice a day, and **Group B** will be administered with aqueous extract of *Eclipta alba* 500 mg with *Rasasindoor*(62 mg) twice a day for 30 days. Sta-

tistical analysis will be done after the last visit of the patient for the anticipative outcome.**Results:** We anticipate that due to *the Yogvahi* action of *Rasasindoor*, group B will show better control of blood pressure as compared to group A.**Conclusion:** *Rasasindoor* has *Yogvahi* (bioenhancer) properties, so it can be used with various types of formulations, which can make the expensive drugs affordable and reduce the toxic effects by reducing the required dose of drugs in the management of different types of disorders.

Keywords: Essential Hypertension, *Rasasindoor, Yogvahi, Eclipta alba*

INTRODUCTION

Hypertension(HTNorHT), also known as high blood pressure or arterial hypertension, is a chronic medical condition in which the blood pressure in the arteries is persistently elevated (1) Hypertension is the most common condition seen in primary care and leads to myocardial infarction, stroke, renal failure, and death if not detected early and treated appropriately(1)Hypertension is a growing problem in India and causes significant burden on the health system. According to data from the GBD study of 2016, hypertension led to 1.63 million deaths in India in the year 2016 alone. (2) Well-managed and well-controlled hypertension leads to a better quality of life and reduces the risk of complications, which include coronary artery disease, heart failure, cerebrovascular disease, and chronic kidney disease. (3)According to the World Health Organization, in 2015, raised BP was responsible for 7.5 **million** deaths, about 12.8 per cent of the total of all deaths globally. The global Burden of Disease (GBD) study of 2016 showed that high systolic BP, defined as >140 mmHg, was the second leading risk factor in terms of attributable disability-adjusted life years (DALYs) in men (122.2 million DALYs) after smoking and the leading risk factor in women (89.9 million DALYs)(4). India has also been experiencing an increase in the prevalence of hypertension. The WHO rates HTN as one of the most important causes of premature death worldwide. According to JNC 8 guidelines, control of B.P. leads to a reduction in every-Approximately 50% reduction in Heart Failure, a 40% reduction in stroke, and about 20-25% reduction in M.I. Only about 25.6% of treated patients had their BP under control in a multicentre study from India on awareness, treatment, and adequacy of control of HTN(5).There are so many references in *Ayurveda* classics that support the presumption that the disease hypertension was present in the ancestral society but in a dormant fashion. Hence the descriptions are scattered here and there, like *Pakshavadha, Sirashula, sotha, mutra Kriccha*, etc. Hypertension is not a very small disease; rather, it affects multiple organ systems and leads to many life-threatening complications. So definitely, it should be a *maharoga*as per ayurveda literature, and that will speak to be whole *vatavyadhi* rather than a fraction or part of it. The disease hypertension does not have a direct correlation with any *Vyadhi* in *ayurvedic* classics, so there is no such *Aushadhiadhikar* for disease hypertension—Chikitsa of any diseases mainly of two types –*Vyadhi Pratyanika and Dosha Pratyanika*. But as Hypertension is a gift of the modern era, its explanation in *Ayurvedic* classics is not available, so *Vyadhi Pratyanika Chikitsa* is not found directly. So, we can focus on *Dosha Pratyanika Chikitsa* for the management of this disease.

PREVALANCE

A cross-sectional, population-based study on a large nationally representative sample of 1.3 million individuals carried out between 2012 and 2014 revealed that the crude prevalence of hypertension in India was 25.3 per cent.During the latter half of the last century, epidemiological studies in India reported that hypertension (diagnosed by systolic blood pressure (BP)⩾160 and/or diastolic BP⩾95 mm Hg) increased from about 1% in the 1950s to 15% in the 1990s in urban (R2= 0.47) and from 0.5 to 7% in rural (R2= 0.21) populations. Hypertension epidemiological studies from India in the last twenty years have shown that prevalence of hypertension (diagnosed by systolic BP⩾140 mm Hg and/or diastolic BP⩾90 mm Hg) in urban locations has stabilized to about 25–30% (R2= 0.08) but it has increased in rural

populations from 15 to 25% (R2= 0.04). (6). A systematic review on the prevalence of HTN in India, for studies published between 1969 and July 2011, reported a range between 13.9 to 46.3% and 4.5 to 58.8% in urban and rural areas of India, respectively. (7) According to the WHO 2008 estimates, the prevalence of raised BP in Indians was 32.5% (33.2% in men and 31.7% in women).

2. RATIONALE OF THE STUDY

Moreover, hypertension is a multifactorial disease. Accordingly, the treatment is diverse. Lots of drugs are already in use, either alone or in combination. Drugs, once started, usually continue lifelong. Hence the research is still on to find a safe, cost-effective, and suitable drug for the treatment of hypertension. Apart from conventional allopathic measures, there must be a meticulous search for alternative treatment; therefore, it is evident to look for natural options & switch to a safer indigenous system of medicine.

WHO (in 1980) has also recommended the evaluation of the effectiveness of plants in conditions where there are no safe, modern drugs available.

3. AIM AND OBJECTIVES

Aim of study-To evaluate the Yogvahi action of *Rasasindoor* with an aqueous extract of *Eclipta alba* in the management of Essential Hypertension.

Objectives of Study

- **Primary:** To evaluate the Yogvahi action of *Rasasindoor* with an aqueous extract of *Eclipta alba* in the management of Essential Hypertension.
- **Secondary:** to evaluate the safety of *Rasasindoor* with an aqueous extract of *Eclipta alba* in the management of Essential Hypertension.

4) CASE DEFINITION

Patients diagnosed as EHT(up to stage 1 according to 7th JNC criteria for Diagnosis of Hypertension systolic blood pressure maximum limit 160 mm of mercury and diastolic blood pressure 100 mm of mercury).

4.1.Research Question-

In order to improve the management of EHT, we wish to know whether *Rasasindoor*(62 mg), due to its *Yogvahi properties* with aqueous extract of *Eclipta alba*(500 mg) twice a day is effective in the management of EHT (upto stage 1 according to 7th JNC criteria for diagnosis of hypertension systolic blood pressure maximum limit 160 mm of mercury and diastolic blood pressure maximum limit 100 mm of mercury).

4.2 Hypothesis

Null Hypothesis(H_0)-*Rasasindoor*is not showing *Yogvahi* action with an Aqueous extract of *Eclipta alba* in the management of Essential Hypertension.

Alternate Hypothesis (H_A)-*Rasasindoor*is showing *Yogvahi* action with an Aqueous extract of *Eclipta alba* in the management of Essential Hypertension.

4.3 STUDY DESIGN

It is a randomized parallel group open trial.

5. METHODOLOGY

5.1 Study Setting

The study will be conducted in MLR AYURVEDIC COLLEGE & HOSPITAL CHARKHI DADRI,HARYANA.

5.2 Registration Number

CTRI/2022/02/040309 is the CTRI registration number for this trial{received on 15/02/2022}

5.3 Diagnostic Criteria- B.P. measurement by Mercury column type. Patients having Blood pressure up to stage 1 according to the 7th JNC criteria for Diagnosis of Hypertension systolic blood pressure maximum limit of 160 mm of mercury and diastolic blood pressure maximum limit of 100 mm of mercury will be selected for the study.

5.4 **Inclusion Criteria**

- ❖ Patients belong to either sex between the age group 30 to 60yrs.
- ❖ Patients who are already diagnosed with E.H.T will be selected.
- ❖ Patients with Stage 1 Hypertension(having systolic B.P. up to 160 and diastolic B.P. upto 100)will be selected for the study.
- ❖ Patients are willing to give written informed consent to participate in the study.

5.5 **Exclusion Criteria**

- ❖ Essential hypertension without any complications.
- ❖ Renal diseases, Diabetic mellitus
- ❖ Pregnancy-induced hypertension.

- ❖ Patients are using drugs like oral contraceptive pills and steroids.
- ❖ Ventricular hypertrophy, secondary hypertension, coarctation of the aorta.
- ❖ Portal hypertension
- ❖ Renal artery stenosis-induced hypertension.
- ❖ Patients who enroll in some other clinical trial.

5.5 GROUPING

No of groups- 2

Controlled group- Group A 50 patients will be given an aqueous extract of *Eclipta alba* 500 mg twice a day.

Trial group- Group B 50 well-diagnosed patients of EHT will be administered with aqueous extract of *Eclipta alba* 500 mg with *Rasasindoor*(62 mg) twice a day for 30 days.

Blinding technique-no

Random allocation method-Randomized computer generated.

Intervention:

Group A

Drug-Aqueous extract of *Bhringraj (Eclipta alba)*, Dosage-500 mg, Packing- Capsule form, Duration-30 days, Anupana-lukewarm water

Group B

Drug-Aqueous extract of *Bhringraj (Eclipta alba)* with *Rasasindoor*

Drug

Aqueous extract of *Bhringraj (Eclipta alba)* 500 mg, *Rasasindoor*-62mg, Packing- Capsule form, Duration-30 days, Anupana-lukewarm water

5.6.1. Follow up.

One month after the completion of the trial for 1 month.

5.6.2. Primary outcomes

To rule out the significant result of *Rasasindoor*with Aqueous extract of *Eclipta alba* in the management of Essential Hypertension.

5.6.3 Secondary outcomes

Change in lab parameters from baseline.

5.7 Statistical Analysis Methods of data analysis

All the data will be collected in the form of measurement or counting. Then inspecting and transforming data with the goal of highlighting useful information suggesting conclusions, and supporting decision-making. Analysis of data will draw valid inferences and make generalizations. Then tabulation of data will be done. Analysis work after tabulation will be based on the computation of various percentages, coefficients, etc. In this study, the sample size is above 30, so the Z-test for quantitative data, Chi-Square for qualitative data, and another suitable test will be used.

5.8 Data Collection Methods

Case registration form with detailed history and examination i.e.

-Consent form in Hindi and English.

-Case Record Form(CRF)

Assessment will be done based on the subjective and objective parameters. In subjective parameters, *Shirshool*(Headache), *Bharma*(Giddiness), *Klama*(Fatigue), *Hrutspandan*(Palpitation), *Swedadhikyata*(Excessive sweating), *Anidra*(Insomnia) will be measured, and in objective parameters blood pressure, pulse rate, haematological test-(Hb, TLC, DLC, ESR), RFTs {serum urea & creatinine, electrolytes(Na+, K+)}, blood sugar (Fasting), lipid profile (Sr.Triglyceride, S.Cholesterol, HDL, LDL, VLDL), urine complete examination (microscopic/macroscopic/chemical), serum uric acid, ECG, chest X-ray.

-Data of all participants will be collected and reported in case sheet form. -We will stay in touch with patients by taking contact numbers and timely advising them for documentation with reason.

6. Expected Result: After the trial, there may be an improvement in subjective and objective parameters.

DISCUSSION

Rasasindoor(red sulfide of mercury) is known in ancient Indian literature as *Rasasindura* (alias *Rasasindura, Rasasindoor, rasasinduram, sindur*, or *sindoor*) and is used extensively in various ailments and diseases. Its *Yogvahi* properties (bioenhancer) are mentioned in *Rasamritum.* Bioenhancer is those phyto molecules that are capable of enhancing the bioavailability and bio efficacy of a particular drug or nutrient with which it is combined without any pharmaco-

logical activity of its own at the dose used. Maximizing bioavailability is therapeutically important because the extent of bioavailability directly influences plasma concentrations and, consequently, therapeutic efficacy. Bioavailability enhancement can make expensive drugs affordable and reduce the toxic effects by reducing the required dose of drugs. A bioenhancer may act by different mechanisms like promoting the absorption of the drugs from the gastrointestinal tract, inhibiting or reducing the rate of biotransformation of drugs in the liver or intestines, modifying the immune system in such a way that the overall requirement of the drug is reduced substantially, etc. Hence this study is proposed to evaluate the Yogvahi action of *Rasasindoor* in the management of Essential Hypertension.

7.1 Dissemination Policy: The data will be disseminated by paper publication: authorship eligibility guidelines and any intended use of professional writers.

Timeline chart /Gnatt Chart/Pert Chart

	2022				2023			
Item	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Registration of patient								
Data collection								
Writing the thesis parts upto methods.								
Data investigation								
Writing the thesis parts upto results and conclusion								
Submission								
-								

7.2 Informed Consent Material: With all the information model consent other related documentation will be provided to the participants.

7.3 Strengths: If the drug combined with *Rasasindoor* due to its *Yogvahi action* will show better control of Essential Hypertension, the drug alone, then it will be a better, cost-effective method for control of Essential Hypertension without any side effects.

8. Limitations: More patients may be registered for better results.

CONCLUSION

Evaluating the *Yogvahi*action of *Rasasindoor*'s present methodology will be easy and cost-effective for the patient with Essential Hypertension. If we get positive results, then the benefit of the *Yogvahi* action of *Rasasindoor* can also be used in the management of other disorders.

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