

Comparative study to evaluate the effect of *rudraksh* (*Elaeocarpus Ganitrus* Roxb.) and *sarpagandha* (*Rauvolfia Serpentine*) in the management of stage i essential hypertension

Rani Mude^{1*}, Vaishali Kuchewar², Shilpa Gaidhane³

¹ PG Scholar, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India

² Professor, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India

³ Professor, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India

Abstract

Background: Hypertension causes a number of vascular disorders and a major cause of cardiovascular problems and chronic kidney damage and stroke, which may cause premature death. Due to the adverse effects as well as resistance of antihypertensive drugs of Modern medicine, there is marked awareness about traditional medicines. In *Ayurveda*, Blood pressure regulation can be understood by functions of *Rakta Dhatu*, *Prana and Vyana Vayu*, *Sadhaka Pitta*, and *Avalambak Kapha*. Various terminologies described in *Ayurveda* can be correlated with hypertension.

Aim: Evaluation of efficacy of *Rudraksh churnakriya* in the management of Stage I essential Hypertension.

Methodology: 40 patients (20 in each group) will receive intervention *Rudraksha churnakriya* (20 patients) and *Sarpagandha Ghana vati* (20 patients)

Result: Lowering down the elevated blood pressure is expected.

Conclusion: *Rudraksh churnakriya* will be more effective than *Sarpagandha Ghana vati*.

Keywords: hypertension, *prana vayu*, *vyana vayu*, *sadhak pitta*, *avalambak kapha*, *rakta dhatu*

Introduction

Hypertension is a lifestyle disease occurs due to stressful psychological conditions and faulty and stressful life style. It is a risk factor for many negative health outcomes, including cerebrovascular disease, heart failure, accelerated atherosclerosis, stroke, renal failure and ventricular hypertrophy [1]. Chances are increased in patient with liver cirrhosis complicated with portal hypertension [2]. Risk factors for atherosclerosis include non-modifiable like physical inactivity, lipid disorder, hypertension, stress [3]. There are mainly two types of Hypertension, Primary and Secondary.

Primary hypertension (unknown etiology) is found in more than 95% cases. In which 25% are rural and 33% are urban are involved [4].

Strategies to reduce the risk of cardiovascular disorders among elderly should be focused on reducing tobacco use and early detection and optimal control of hypertension [5]. Various terminologies described in *Ayurveda* can be correlated with hypertension like *Siragata Vata*, *Raktamad*, *Raktagata Vata*, *Vyana Prakopa*, etc. In each of these terms, the main pathogenesis occurs in *Rakta* along with dhamani (blood vessels) [6].

In Modern treatment, there are several types of drugs used to treat Hypertension, including Calcium channel blockers, ACE inhibitors, Thiazide diuretic, ARBs, Renin inhibitors, Beta-blockers and Combination medications [7]. A number of studies had been found on Hypertension in this region of Wardha District [8, 9, 10, 11, 12, 13, 14, 15, 16]. While searching the herbs available for hypertension, many herbs like *Jatamansi*, *Sarpagandha*, *Ashwagandha*, *Arjun*, *Punarnava*

are found. *Rudraksh* (*Elaeocarpus ganitrus*) is one of them on which multiple animal studies are available. In *RajNighantu*, *Rudraksh* is mentioned as *Vata-Kaphashamak* and *Bhutagraha vinashak*.

The aim of the study is to critically analyse various terms used in ayurveda which has some similarity of signs and symptoms related to Hypertension, to study the effect of *Rudraksh churnakriya* on SBP and DBP and to study the effect of *Rudraksh churnakriya* on pulse rate and rhythm.

Trial Design

Randomized active control open clinical trial. Interventional study, 2 parallel group are taken. Ratio is 1:1.

Methodology

Study Setting

The study will be conducted in MGAC, Hospital & Research Centre, Salod (H), and Wardha.

Eligibility Criteria

Patients aged between 30 to 60 years irrespective of sex. Stage I essential Hypertension (Systolic pressure - 130-139 mmHg and/or Diastolic pressure - 80-89 mmHg) – on measuring blood pressure with Mercury sphygmomanometer on three different occasions in a day. Stage I essential Hypertension with controlled Diabetes mellitus will be taken in inclusion criteria. And Hypertensive crisis: Systolic over 180 and/or diastolic over 120, Hypertension with: Cardio-vascular diseases, Cerebro-vascular diseases, Hypothyroidism, Pregnant and lactating women will be taken in exclusion criteria.

Interventions

Table 1

Sr. no.	Intervention	Dose	Anupana	Kala	Frequency
1.	Rukdraksh churnakriya	500 mg	Koshna jala	Pragbhakta	Twice a day
2.	Sarpagandha Ghana vati	500 mg	Koshna jala	Pragbhakta	Twice a day

Criteria for Discontinuing or Modifying Allocated Interventions

If any unexpected incidence, any problem, other disease or drug sensitivity features arises, then the subject will be withdrawn from the study and till the problem subsides free treatment will be provide.

We will measure number of tablets for the consumption of appropriate dose for assessment and to check drug adherence, during 30 days of treatment the subject will be followed up.

Follow up Period after Treatment

37th day, 45th day

Normal routine diet and no precaution for food intake is advised to the patient.

Primary Outcomes

Interventional drug effect on SBP, DBP and Pulse pressure (SBP –DBP)

Secondary Outcomes

We will see reoccurrence and any adverse effect of interventional drug.

Statistical Analysis

Analysis of baseline changes with by applying paired and unpaired student “t” test.

Time Duration till Follow Up

During treatment of 30 days patient will be followed up. : 7th, 15th, 21st, 30th, 37th and 45th day.

Time Schedule of Enrolment, Interventions

Time for giving drug will be from 0 to 30 days and after that follow up on 37th and 45th day.

Sample Size

40 (In each group 20)

Recruitment

Simple random sampling.

Methods

Lottery method.

Implementation

Enroll the subject after allocate PI.

Methods

Data collection method then after management and lastly analysis.

Data collection Methods

Assesement Criteria

Measurement of Systolic and Diastolic blood pressure on 7th day, 15th day, 21st day, 30th day (during treatment) and On

37th & 45th day (after treatment) with Mercurial sphygmomanometer.

Objective Criteria

SBP, DBP and Pulse pressure (SBP –DBP=PP)

We will keep in contact with patient by his contact no. and recall them for timely medication and timely follow up will be taken. Storage of this follow up data will be keep in documentation form with reason.

Data Management

By using PI data entry will be coded.

Statistical Methods

Paired and unpaired student ‘t’ test

Plans to Promote Participants Retention and Complete Follow Up

We will stay in touch with patient by taking contact no. and timely advise them for medication and follow up and data of follow up patient will be stored in documentation with reason.

Data Management

The data will be collected from patients by assessor by doing clinical assessment after taking written consent form from the patient data will be collected using structured questionnaire filled during interview of the patient. Data will be entered in master sheet and analyzed by using appropriate statistical technique and data coding will be done by principal investigator.

Ethics and Dissemination

Approval from Research ethics; Research ethics committee has taken. Ref. No- DMIMS (DU)/IEC/Jun-2019/8029

Consent or Assent

Patient’s written consent will be take.

Confidentiality of the patient during the whole study will be maintained.

Dissemination Policy

Through paper publication dissemination of data will be done. Professional writers and Authorship eligibility guidelines will be used.

Informed Consent Materials

Informed consent to each patient is given written in English and local language consisting of all the detail about drug and study and contact no. and address of principal investigator. Model consent form given to the participants with documentation with all the information.

Expected Results

Multiple reviews and animal study are available on *Rudraksh*, but no any human study is available. So, it will be an experimental study on human being. After searching

literature review, it is found that *Rudraksh* is having that properties which can control the elevated blood pressure. It is lowering down the elevated Systolic and Diastolic blood pressure is expected.

Discussion

High blood pressure is called as Hypertension in Modern science. There is no any disease in *Ayurveda* which completely resembles with hypertension but under certain headings the nomenclature is possible by taking the support of sign and symptoms. There is no specific cause for Arterial hypertension is called as essential hypertension or primary hypertension. Possible causes for Secondary hypertension are that conditions which affects arteries, heart and kidneys. Primary hypertension is having unknown etiology and it is found in most of the cases.

Stressful psychological conditions and faulty life style may be the considerable causes for primary hypertension. In *RajNighantu*, *Rudraksh* is mentioned as *Vata-Kaphashamak* and *Bhutagraha vinashak*. It is also given as *Raktabharshamak* and *Mastishka shamak* [18]. In the animal study on rats, shows that *E. ganitrus* extract have significant antihypertensive activity [19]. So, we can consider that *Rudraksh* will be useful in the treatment of Hypertension. In this article, it is hypothesized that *Rudraksh* may be effective in the management of Hypertension. Many articles related to hypertension and different factors in this region were reviewed [20-24].

Conclusion

Hypertension can be controlled with the help of proper planning of herbal medications without any harmful side effects. *Rudraksh churnakriya* will be more effective than *Sarpagandha Ghana vati*.

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