



Clinical Research

A pilot study to clinically evaluate the role of herbomineral compound “*Rakatchap Har*” in the management of essential hypertension

Ruchika Nandha¹, Harpal Singh², Parminder Moudgill³, Gurpreet Kular⁴

¹Department of Pharmacology, Dr. Harvansh Singh Judge Institute of Dental Sciences, Chandigarh, ²Department of Anaesthesia, Fortis Hospital, Mohali, ³General Physician, Ludhiana, ⁴Department of Pharmacology, Govt. Medical College, Amritsar, Punjab, India

Abstract

The aim of the present study was to investigate the clinical efficacy of a herbomineral medicine *Rakatchaphar* (Each 500 mg cap contains *Sarpgandha* 150 mg, *Shankhpushpi* 75 mg, *Jatamansi* 75 mg, *Jahar Mohra Khatai Pishti* 75 mg, *Moti Pishti* 75 mg, *Ras Sindoor* 50 mg) in essential hypertension, an observational prospective study was done at Shri Ashutosh Maharaj (SAM) Ayurvedic Treatment and Research Centre, Noormahal. Ninety-eight patients in the age group 28–76 years with essential hypertension without any co-morbid illness were included in the study. Patients were treated with cap *Rakatchaphar* 500 mg twice a day. Blood pressure (BP) was monitored on subsequent follow-up visits at 2, 4, 6, and 8 weeks. Change in Diastolic BP (DBP), Systolic BP (SBP), and Mean BP (MBP) were analyzed statistically by Student's *t* test, ANOVA, and Post hoc Bonferroni test. On first visit the mean SBP, DBP, and MBP was 164.16±17.27, 101.88±9.20, and 122.27±10.57 mm Hg, respectively. After 8 weeks of therapy there was a statistically significant fall in SBP (122.98±11.36), DBP (80.90±8.57), and MBP (94.86±9.24) in mmHg (*P* value <0.0001). *Rakatchap Har* offers an efficacious and safe combination of natural products available for the treatment of hypertension.

Key words: Blood pressure, hypertension, *Rakatchap Har*

Introduction

Hypertension is the leading member of group of so-called “noncommunicable diseases” and a leading contributory cause of death worldwide.^[1] It is a major health issue affecting <10% of patients up to the age of 34 years and >50% of population after the age of 65 years.^[2] High blood pressure (BP) has estimated to have caused 7.6 million premature deaths and contributed to 92 million disability adjusted life years (DALYs) worldwide in 2001.^[3]

Until 1940, a majority of cardiovascular diseases were treated

Note: The formulation ‘*Rakatchap Har*’ is a registered formulation. The term “*Raktachapa Hara*” is found in Ayurvedic classics. The term used in the article (*Rakatchap Har*) appears to be of local accent.

Address for correspondence: Dr. Ruchika Nandha, Department of Pharmacology, Dr. Harvansh Singh Judge Institute of Dental Sciences, Panjab University, Chandigarh, India.
E-mail: rmandha23@yahoo.co.in

with traditional drugs obtained from plants, but with time, entry of conventional modern medicine has overshadowed the phytopharmaceutical products.^[4] In lieu of the fact that the incidence of hypertension is still rising alarmingly, there is dire need to search for an effective and safe magical remedy because of lack of current therapies to either provide complete cure or treating the patients at the cost of adverse effects.^[5-7]

Already a comprehensive search of scientific literature has identified natural health products capable of lowering BP.^[8] Natural treatment of essential hypertension along with life style modifications can bring down the blood pressure values into the normal range.^[9,10] Hence there is the need for resurgence of the use of traditional medicines by switching onto the older systems of *Ayurveda* from current therapies.^[4] In the present context, the Ayurvedic system of medicine is widely accepted and practiced not only in Indian peninsula but also in developed countries.^[11] *Ayurveda* sees hypertension as imbalance of *tridosha Vata, Pitta, and Kapha* so treatment by *Ayurveda* targets on correction of these doshas.

Rakatchap Har (means which nullifies hypertensive effect) is also such an addition to the long list of current antihypertensive medications which can prove to improve BP in all grades

of hypertension effectively by synergistic effects of all the six components in it. The present study highlighted on the antihypertensive efficacy of *Rakatchap Har*. It is a new drug approved by Department of Ayurveda, Govt. of Punjab, showing dramatic improvement in BP in clinical practice. Reason for the selection of this drug is lack of clinical trials in spite of its dramatic efficacy as antihypertensive.

Materials and Methods

It was a prospective observational study done at Shri Ashutosh Maharaj (SAM) Ayurvedic Treatment and Research Centre, Noomahal. Approval was taken by the Ethics Committee before starting the study. Informed consent was taken from each patient for participation in the study. 110 patients of recently diagnosed essential hypertension were selected to be followed-up after giving them *Rakatchap Har* 500 mg twice a day. The study was completed with 98 patients, as 12 patients did not come for follow-ups. As this study was done in a charitable unit with patients coming from low socioeconomic strata with low literacy, they were not aware of the importance of follow-up visits. So those were the drop out cases of the study.

Patients were involved irrespective of their age, sex, occupation, social status, ethnicity, and grade of hypertension. All the patients who were already undergoing some antihypertensive treatment, with secondary/malignant hypertension, pregnancy, heart failure, diabetes mellitus, bronchial asthma, peripheral vascular disease, significant hepatic or renal dysfunction have been excluded from the study. For assessing their eligibility, all of them underwent complete physical examination, chest X-ray, ECG, blood biochemistry, and urine analysis. So all the patients included had investigations within normal limits.

Patients were categorized according to JNC7 classification of hypertension into prehypertensive, stage I and stage II,^[12] and were prescribed *Rakatchap Har* 500 mg twice a day with lukewarm water. All the patients were motivated for life style modifications (adequate exercise, salt restriction in diet, smoking cessation, avoidance of alcohol intake) and given psychotherapy (through counseling sessions and orienting them toward yoga and meditation techniques) to distress them, as this aspect is equally important in the management of hypertension. All the patients attended the clinic at 2 weekly intervals at 2, 4, 6, and 8 weeks. Each time BP was measured by the same person to reduce the subjective error. BP measurements were taken uniformly after rest for at least 5 min and in sitting position in the right arm using same zero mercury sphygmomanometer on each visit. The 1st and 5th Korotkoff's sounds were used to determine Systolic BP (SBP) and Diastolic BP (DBP). At each visit SBP, DBP, and mean BP (MBP) were recorded. MBP was calculated as $DBP + PP/3$ ($PP = \text{Pulse Pressure}$). Results were statistically analyzed at the end of the study by Student's *t* test, ANOVA, and Post hoc Bonferroni test. *Rakatchap Har* has been prepared by SAM Ayurvedic Treatment and Research Centre's own pharmacy by standardized manner after mixing the appropriate amount of each component as given below. Each 500 mg capsule contains

<i>Sarpagandha</i> (<i>Rauwolfia serpentina</i>)	Root	150 mg
<i>Shankhpushpi</i> (<i>Convolvulus pluricaulis</i>)	Whole Plant	75 mg
<i>Jatamansi</i> (<i>Nardostachys jatamansi</i>)	Root	75 mg

<i>Jahar Mohra Khatai Pishti</i> (Serpentine stone)	Powder	75 mg
<i>Moti Pishti</i> (Margarita)	Powder	75 mg
<i>Ras Sindoor</i> (Plumbioxidum rubrum)	Powder	50 mg

Observation and Results

Ninety-eight patients completed the study. Patients were of the age group 28–76 years. The mean age of the patients was 50.45 ± 10.27 years with 40 (40.8%) patients <50 years and 58 (50.2%) patients >50 years. There were 54 (55.1%) males and 44 (44.9%) females. Of all the patients involved 4 (4.1%) were prehypertensive, 22 (22.4%) were with stage I hypertension, and 72 (73.5%) with stage II hypertension.

On first visit the mean SBP, DBP, and MBP was 164.16 ± 17.27 , 101.88 ± 9.20 , and 122.27 ± 10.57 mmHg, respectively. Clinically significant improvement in BP was seen within 2 weeks after starting the therapy in 92% of patients. At each visit, there was a statistically significant fall in SBP, DBP, and MBP (P value < 0.0001) using Bonferroni Post Hoc test [Table 1 and Figure 1].

The Mean SBP was 138.9 ± 17.65 , 130.9 ± 14.05 , 125.1 ± 20.51 , and 122.98 ± 11.36 mm Hg at 2, 4, 6, and 8 weeks, respectively.

The Mean DBP was 89 ± 9.28 , 83.8 ± 7.47 , 85.2 ± 10.65 , and 80.9 ± 8.57 mm Hg at 2, 4, 6, and 8 weeks, respectively

The Mean MBP was 105.8 ± 11.12 , 99.5 ± 9.48 , 98.1 ± 9.79 , and 94.86 ± 9.24 mm Hg at 2, 4, 6, and 8 weeks, respectively [Table 1].

The decrease in mean SBP, DBP, and MBP was more in Stage II hypertension as compared to Stage I hypertension at all intervals of time. At the end of the study, Mean SBP was reduced by 28.1% in Stage II hypertension patients as compared to 13.9% reduction in patients with Stage I hypertension. Reduction in mean DBP was 23.4% in Stage II patients as compared to 9.5% in Stage I patients. Mean MBP was reduced by 25.5% in Stage II patients as compared to 11.3% reduction in Stage I patients (Student's *t* test) [Table 2].

In both females and males change in mean SBP, DBP, and MBP was analyzed by ANOVA test and found to be statistically significant (P value < 0.0001) at each visit [Table 3]. Gender did not appear to significantly affect the responsiveness to the drug. No clinically significant adverse drug reaction was

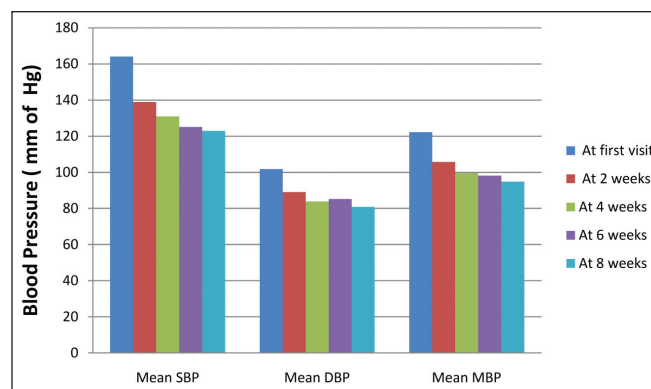


Figure 1: The change in blood pressure with the trial drug over observation period

Table 1: Statistical analysis of the effect of *Rakatchap Har* on blood pressure

	At first visit	After 2 weeks	After 4 weeks	After 6 weeks	After 8 weeks	P value
Systolic blood pressure (mmHg)	164.16±2.468	138.98±2.521	130.96±2.008	125.16±2.93	122.98±1.624	<0.0001
Diastolic blood pressure (mmHg)	101.8±1.315	89.04±1.326	83.84±1.067	85.20±1.523	80.90±1.225	<0.0001
Mean blood pressure (mmHg)	122.27±1.511	105.8±1.590	99.59±1.356	98.18±1.399	94.86±1.321	<0.0001

The Mean ± SEM values of the Systolic, Diastolic, and mean blood pressures of patients at first visit and after 2, 4, 6, and 8 weeks of treatment with 500 mg BD of *Rakatchap Har*

Table 2: Percentage change in blood pressure according to stage of hypertension

	Stage of hypertension	After 2 weeks	After 4 weeks	After 6 weeks	After 8 weeks
Percentage change in systolic blood pressure	Stage I	-10.982±2.969	-10.985±2.709	-13.112±2.906	-13.968±2.894
	Stage II	-16.946±1.606	-22.844±1.536	-26.510±2.363	-28.178±1.427
Percentage change in diastolic blood pressure	Stage I	-5.010±4.344	-9.158±3.349	-7.584±4.879	-9.517±4.717
	Stage II	-14.595±1.557	-19.784±1.525	-18.413±1.955	-23.430±1.318
Percentage change in mean blood pressure	Stage I	-7.668±3.320	-9.510±2.743	-11.370±3.651	-11.361±3.638
	Stage II	-15.341±1.369	-21.098±1.391	-21.867±1.297	-25.544±1.215

The percentage change ± SEM values of the Systolic, Diastolic, and mean blood pressures of patients at first visit and after 2, 4, 6, and 8 weeks of treatment in Stage I and II of hypertension (JNC7) with 500 mg BD of *Rakatchap Har*

Table 3: Statistical analysis of mean change in blood pressure (mm Hg) in females and males

		At first visit	After 2 weeks	After 4 weeks	After 6 weeks	After 8 weeks	P value
Females	Mean systolic blood pressure	164.73±3.382	138.09±2.836	131.14±2.686	120.64±5.622	120.45±2.372	<0.0001
	Mean diastolic blood pressure	101.09±1.527	89±2.042	83.82±1.367	85.05±2.121	80.18±2.182	<0.0001
	Mean blood pressure	122±1.807	105.41±2.105	99.55±1.717	97.82±2.122	93.50±2.194	<0.0001
Males	Mean systolic blood pressure	163.70±3.586	139.70±3.995	130.81±2.961	128.85±2.608	125.04±2.184	<0.0001
	Mean diastolic blood pressure	102.52±2.055	89.07±1.774	83.85±1.608	85.33±2.192	81.48±1.365	<0.0001
	Mean blood pressure	122.48±2.345	106.15±2.354	99.63±2.054	98.48±1.893	95.96±1.603	<0.0001

Mean ± SEM values of the systolic, diastolic, and mean blood pressures of female and male patients at first visit and after 2, 4, 6, and 8 weeks of treatment

seen in patients taking *Rakatchap Har*. Out of 98 patients, 3 experienced mild headache and 2 felt fatigue.

Discussion

Nowadays treatment of hypertension is governed by established goals given by JNC7 recommendations. In spite of it, not all the patients are having controlled hypertension irrespective of the use of antihypertensive medications. Main reasons are poor patient compliance and adverse effects by antihypertensive drugs.^[13] Many phytopharmaceutical products have been proven to be successful in treating hypertension as *Ayurveda* enjoys the advantage of curing a disease causing minimal adverse effects. Recently, interest in herbal medicines has been rejuvenated and studies are being carried out to prove the clinical efficacy of compound preparations.^[14] The trial drug *Rakatchap Har* is also a herbomineral preparation, which has been formulated taking into consideration the drawbacks of conventional antihypertensive medications. The trial drug contains 6 ingredients, which have been selected for their peculiar qualities to be added for the treatment of hypertension. *Sarpagandha* (*Rauwolfia serpentina*), which is the main constituent, has antiadrenergic and antidepressant property and is a well-proven antihypertensive.^[4,5,15] *Shankhpushpi* (*Convolvulus pluricaulis*) is a

medhya rasayan, which controls the production of stress hormones. Its ethanolic extract has been found to reduce cholesterol, triglycerides, and phospholipids. Being an antioxidant also, its use in cardiovascular diseases (CVD), such as hypertension is known. Its stress lowering effect adds to its antihypertensive action.^[16] *Jatamansi* (*Nardostachys jatamansi*) is another herb, oily extract of which has been found to have antioxidant, anti-ischemic, and antiarrhythmic potential. It also increases high-density lipoprotein levels, which are protective lipids.^[17] A few studies have also mentioned its anxiolytic action.^[16] *Jahar Mohra* and *Moti Pishti* studies in hypertension are not too much but are known remedies for CVD.^[18,19] *Ras sindoor* also contributes to decrease high BP by its mind calming effects.^[20] Thus the synergistic action of all these is resulting in a high efficacy and high potency antihypertensive remedy "*Rakatchap Har*." Treatment with *Rakatchap Har* has produced an early, sustained, and significant fall in BP. Clinically and statistically significant fall in BP was seen early at 2 weeks in comparison to other herbal formulations studied for their antihypertensive effect.^[2,7,21] Normotensive effect of the drug in terms of SBP and DBP was observed in all the patients. Results were better in Stage II than in Stage I, reflecting its high efficacy in regulating BP. Age or gender did not significantly affect the responsiveness to study drug.

Emphasis has been given on life style modifications by motivating each patient personally at each visit, without ignoring the important aspect of psychotherapy to distress the patient. Alone general measures have not so far been able to treat Stage I and Stage II hypertension. So such dramatic improvement in mild to the severe forms of hypertension can be attributed to the trial drug. For further evidence future comparative studies will be done.

In addition to demonstrating superior rate of blood pressure goal achievement with *Rakatchap Har*, this study demonstrated minimal adverse effects, such as mild headache and fatigue with treatment.

Major drawback of this study is that no controls have been taken to compare its efficacy. Explanation being the preliminary stage of research in the antihypertensive activity of *Rakatchaphar Har*. Further studies will be followed to assess the comparative efficacy with already existing antihypertensive medications.

Conclusion

Rakatchap Har along with life style modification and psychotherapy is a safe and efficacious remedy for the treatment of all grades of hypertension in all age groups with no limitation to its use.

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हिन्दी सारांश

उच्चरक्तचाप रोग में आयुर्वेदिक औषधि 'रक्तचाप हर' के प्रभाव का अध्ययन

रुचिका नंधा, हरपाल सिंह, परमिन्दर मुद्गिल, गुरप्रीत कुलर

हृदयरोग समाज में सबसे अधिक मृत्युदर का कारण है। जिसमें मुख्य भूमिका रक्तचापाधिक्य की है। यह पाश्चात्य एवं पूर्वी देशों के लोगों का अग्रणी रोग बनकर सामने आया है। इस रोग के बढ़ते प्रभाव के कारण एक ऐसी औषधि की आवश्यकता सामने आती है, जो इस रोग में अत्यन्त प्रभावकारी हो तथा जिसके कुप्रभाव नगण्य हों। आधुनिक चिकित्सा पद्धति (Allopathy) में वर्णित एवं उपयुक्त रक्तचाप को कम करने वाली (Antihypertensive) दवाईयाँ इस संदर्भ में अनुकूल प्रतीत नहीं होती हैं, क्योंकि इनके उपयोग से शरीर में कई प्रकार के दुष्प्रभाव देखने को मिलते हैं। विभिन्न अविष्कारों से यह बात साक्ष्य हुई है कि अन्य पद्धतियाँ भी इस रोग में प्रभावकारी हैं, उनमें से एक है – आयुर्वेदिक प्राकृतिक औषधियों का प्रयोग। रक्तचापहर इनमें से एक है। यह आयुर्वेदिक औषधि प्रभावशाली तरीके से रक्तचापाधिक्य को कम करती है। इस लेख में इस औषधि के उन गुणों का वर्णन एवं मूल्यांकन साक्ष्य सहित है, जो कि इस औषधि को इस रोग में अत्यन्त प्रभावकारी, गुणकारी एवं कुप्रभावरहित बनाते हैं।